

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

CONMED CORPORATION

Plaintiff,

Civil Action No. 6:13-CV-1226 (GTS/TWD)

v.

JURY TRIAL DEMANDED

IOAN COSMESCU and
I.C. MEDICAL, INC.

Defendants.

FIRST AMENDED COMPLAINT

Plaintiff ConMed Corporation (“ConMed”), by and through its attorneys, Bond, Schoeneck & King, PLLC, hereby alleges as its Complaint against the defendants Ioan Cosmescu (“Cosmescu”) and I.C. Medical, Inc. (“I.C. Medical”) (collectively “Defendants”) as follows:

JURISDICTION AND VENUE

1. This is a declaratory judgment action for non-infringement and invalidity of a patent, brought under the Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202, and the Patent Act, 35 U.S.C. §§ 271 *et seq.*

2. This Court has subject matter jurisdiction in this action pursuant to 28 U.S.C. § 1331 and 1338(a), and §§ 2201(a) and 2202.

3. Personal jurisdiction is proper in this District by virtue of Defendants' threats of infringement made against ConMed. Upon information and belief, Defendants expected or should have reasonably expected its acts to have consequences in this District and Defendants derives substantial revenue from interstate or international commerce.

4. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

5. There is an actual justiciable case or controversy between ConMed and Defendants in this district that arises under the patent laws, 35 U.S.C. §§ 101 *et seq.*, by virtue of Defendants' accusation that ConMed is infringing its U.S. patent rights.

FACTS

6. Plaintiff ConMed is a New York corporation headquartered at 525 French Road in Utica, New York that specializes in orthopedics and general surgery products. Since its founding in 1973 as small, privately held company, ConMed has grown into a large, publicly held and diversified medical device organization that manufactures thousands of products and employs over 3,000 people in multiple manufacturing facilities and sales offices worldwide.

7. Defendant Cosmescu is an individual and the owner of U.S. Patent No. 7,935,109 (the '109 patent), a copy of which is attached hereto as **Exhibit A**, which is directed to certain multifunctional electrosurgery pencils having bipolar electrodes. Defendant Cosmescu is also the owner of U.S. Patent No. 8,414,576 (the '576 patent), a copy of which is attached hereto as **Exhibit B**, which is directed to certain electrosurgery pencils having swivels.

8. Defendant I.C. Medical is a corporation organized and existing under the laws of the Arizona and having a principal place of business at 2340 West Shangri La Road, Phoenix, Arizona 85029. Defendant Cosmescu is the founder and President of Defendant I.C. Medical

and, upon information and belief, Defendant I.C. Medical is the exclusive licensee of the '109 and '576 patents and/or has been granted the right to enforce the '109 and '576 patents against third parties.

9. ConMed is currently offering to sell and selling certain monopolar electrosurgical pencils throughout the United States, including a monopolar electrosurgical pencil referred to as the GoldVac® electrosurgery pencil ("the Accused Product").

10. On or about September 5, 2013, counsel for Defendant I.C. Medical notified ConMed by written correspondence that, in the opinion of Defendants, the Accused Products infringe the claims of the '109 patent. A true and correct copy of the correspondence dated September 5, 2013 is attached hereto as **Exhibit C**.

11. In response to correspondence dated September 15, 2013 from ConMed that disputed the allegations of infringement, Defendant I.C. Medical again wrote to ConMed on September 30, 2013 and reasserted its claim that ConMed was infringing the '109 patent. A true and correct copy of the correspondence dated September 30, 2013 is attached hereto as **Exhibit D**.

12. On or about October 5, 2013, counsel for Defendant I.C. Medical notified ConMed by written correspondence that, in the opinion of Defendants, the Accused Products also infringe at least one claim of the '576 patent. A true and correct copy of the correspondence dated October 5, 2013 is attached hereto as **Exhibit E**.

13. Based on Defendants' threats of infringement, ConMed has a reasonable apprehension that it will face a patent infringement lawsuit if it continues to offer to sell and sell the Accused Products, which ConMed is current doing and intends to do in the future.

14. In light of ConMed's continuing sale of the Accused Products and Defendants' express accusations that such products are infringing its rights in the '109 and '576 patent, a real and substantial controversy exists between parties' having adverse legal interests.

15. ConMed does not have an adequate remedy at law.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '109 PATENT

16. Upon information and belief, the Accused Products do not contain each and every element of any one claim of the '109 patent.

17. ConMed is therefore entitled to a declaratory judgment that the claims of the '109 patent are not infringed.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY OF THE '109 PATENT

18. Upon information and belief, the claims of the '109 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

19. As a result, ConMed is entitled to a declaratory judgment that the claims of the '109 patent are invalid.

COUNT III

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '576 PATENT

20. Upon information and belief, the Accused Products do not contain each and every element of any one claim of the '576 patent.

21. ConMed is therefore entitled to a declaratory judgment that the claims of the '576 patent are not infringed.

COUNT IV

DECLARATORY JUDGMENT OF INVALIDITY OF THE '576 PATENT

22. Upon information and belief, the claims of the '576 patent are invalid under 35 U.S.C. §§ 102, 103 and/or 112.

23. As a result, ConMed is entitled to a declaratory judgment that the claims of the '576 patent are invalid.

PLAINTIFF DEMANDS A TRIAL BY JURY

WHEREFORE, the plaintiff prays that the Court:

- (a) enter judgment that the claims of U.S. Patent No. 7,935,109 are not infringed by the accused product;
- (b) enter judgment that the claims of U.S. Patent No. 7,935,109 are invalid under the Patent Act, 35 U.S.C. §§ 102, 103 and/or 112;
- (c) enter judgment that the claims of U.S. Patent No. 8,414,576 are not infringed by the accused product;
- (d) enter judgment that the claims of U.S. Patent No. 8,414,576 are invalid under the Patent Act, 35 U.S.C. §§ 102, 103 and/or 112;
- (e) enter judgment that this is an exceptional case under 35 U.S.C. § 285.
- (f) award the plaintiff its costs and attorneys' fees; and
- (g) grant the plaintiff such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/David L. Nocilly

Dated: October 23, 2013

By: _____
David L. Nocilly, Bar Roll No. 510,759

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EXHIBIT A

US007935109B2

(12) **United States Patent**
Cosmescu(10) **Patent No.:** **US 7,935,109 B2**(45) **Date of Patent:** ***May 3, 2011**(54) **MULTIFUNCTIONAL TELESCOPIC
MONOPOLAR/BIPOLAR SURGICAL DEVICE
AND METHOD THEREOF**(76) Inventor: **Ioan Cosmescu**, Phoenix, AZ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 981 days.

This patent is subject to a terminal disclaimer.

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(21) Appl. No.: **11/465,197**(22) Filed: **Aug. 17, 2006**(65) **Prior Publication Data**

US 2006/0276783 A1 Dec. 7, 2006

Related U.S. Application Data

(63) Continuation of application No. 10/796,748, filed on Mar. 8, 2004, now Pat. No. 7,112,199, which is a continuation-in-part of application No. 09/977,408, filed on Oct. 15, 2001, now Pat. No. 6,702,812, which is a continuation of application No. 09/088,386, filed on Jun. 1, 1998, now Pat. No. 6,355,034, which is a continuation of application No. 08/717,494, filed on Sep. 20, 1996, now abandoned.

(51) **Int. Cl.**
A61B 18/18 (2006.01)(52) **U.S. Cl.** **606/41**; 606/46; 606/48; 606/50(58) **Field of Classification Search** 606/41, 606/45-50; 604/21, 22, 30, 35, 113, 114
See application file for complete search history.(56) **References Cited****U.S. PATENT DOCUMENTS**

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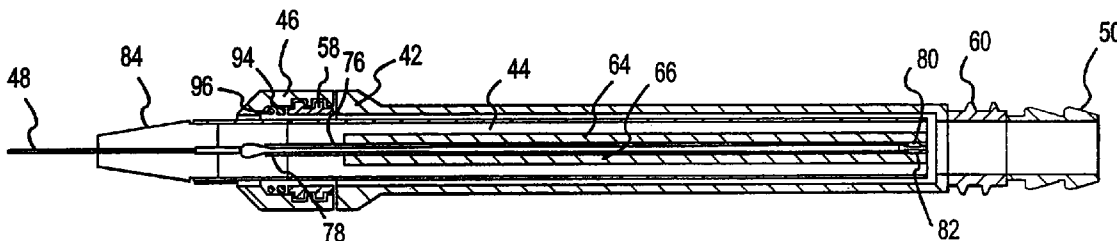
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(Continued)

Primary Examiner — Roy D Gibson(74) *Attorney, Agent, or Firm* — Zeman-Mullen & Ford, LLP(57) **ABSTRACT**

A multifunctional telescopic monopolar/bipolar electrosurgery pencil is disclosed for use with an electrosurgery unit (ESU). The monopolar/bipolar electrosurgery pencil includes a bipolar electrode having an insulator sandwiched between an active electrode and a return electrode wherein the bipolar electrode is connected to a handpiece capable of alternately effectuating cutting and coagulation with the bipolar electrode. The monopolar/bipolar electrosurgery pencil is capable of functioning as both a monopolar and bipolar device and can be used for open and closed laparoscopic and endoscopic procedures. Telescopic means for adjusting the length of the bipolar electrode is also provided as are means for smoke evacuation and suction/irrigation. The multifunctional telescopic monopolar/bipolar device can also be adapted for use with an ESU argon beam coagulator.

10 Claims, 7 Drawing Sheets

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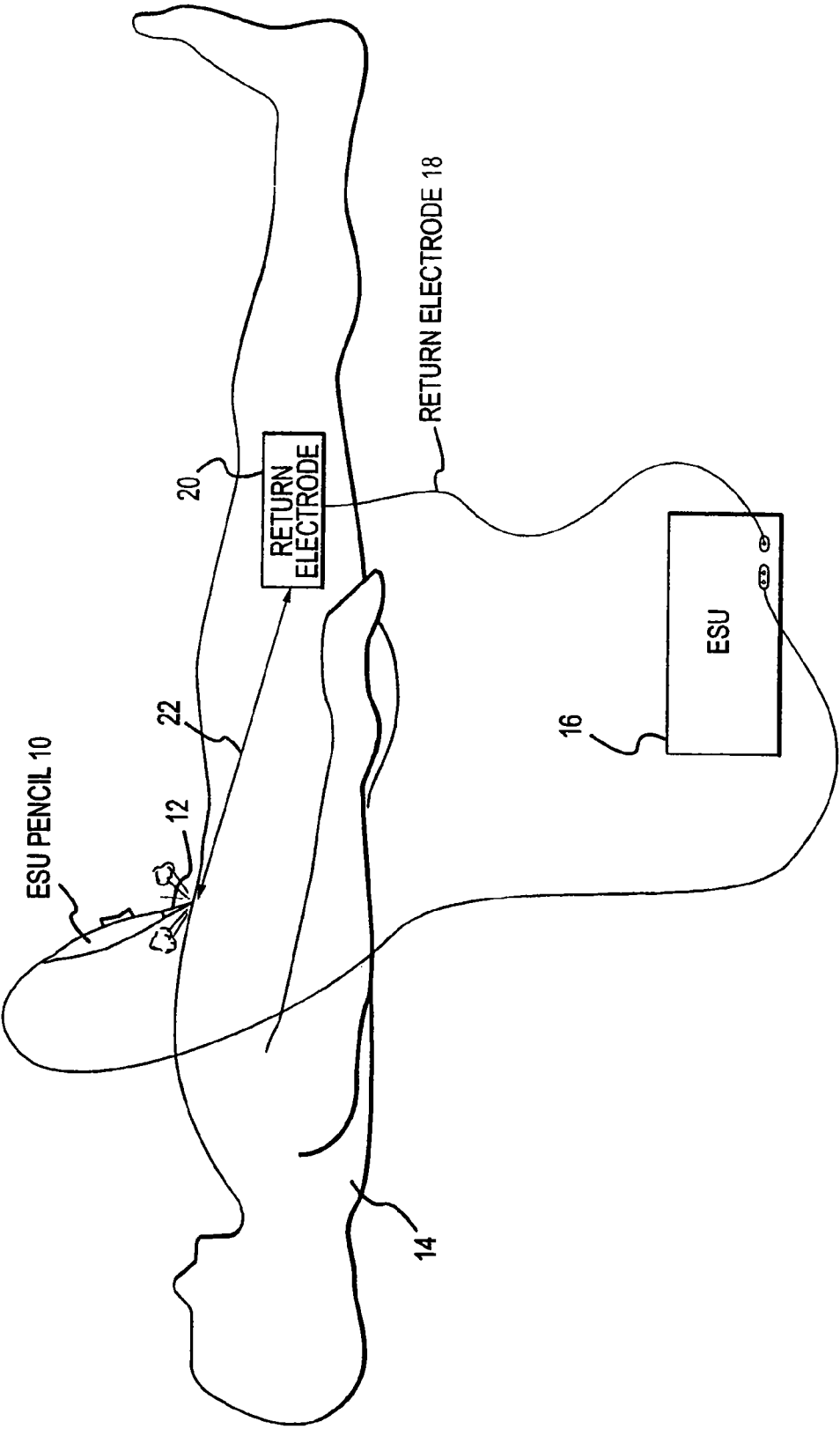


FIG.1a

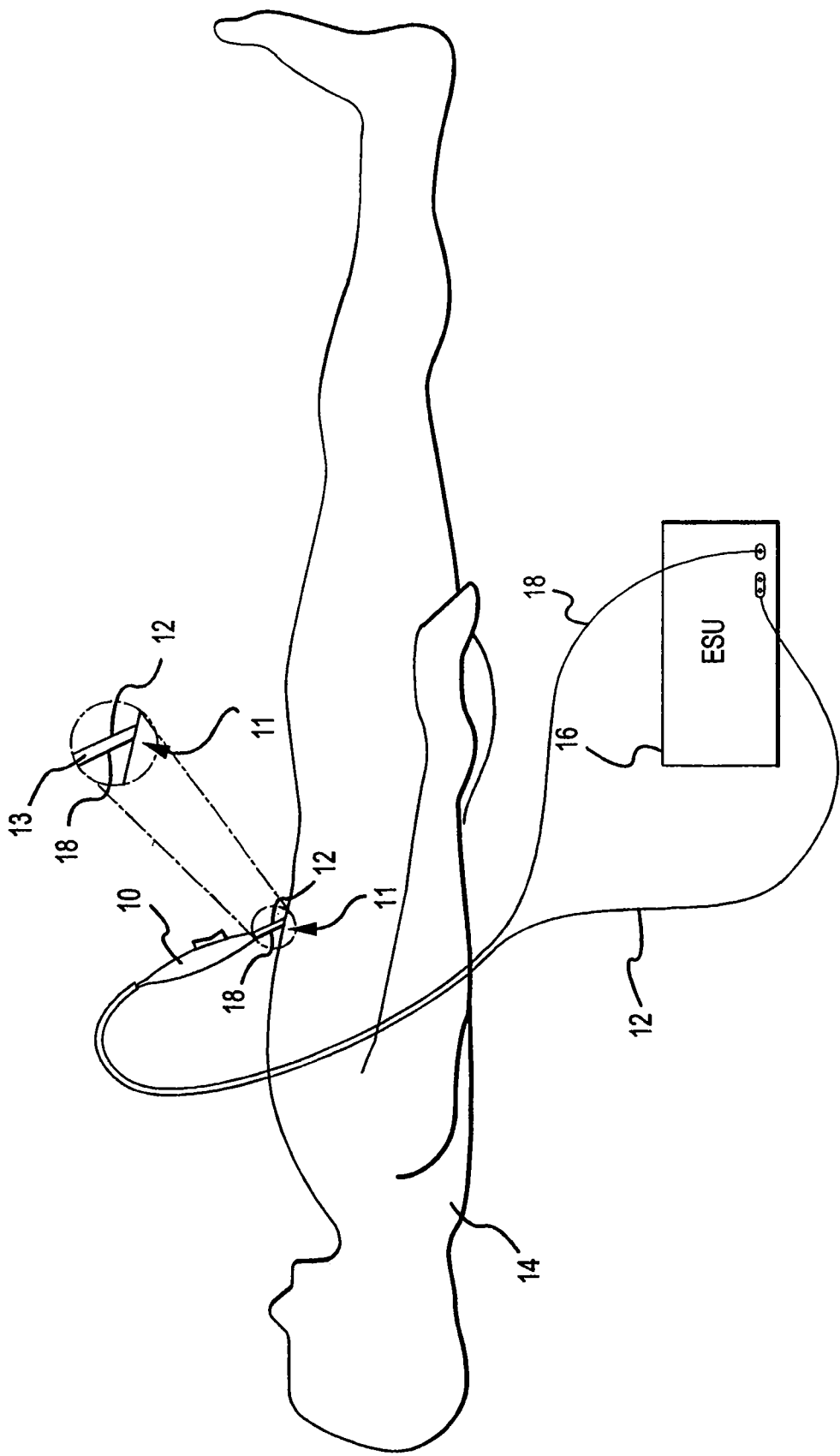


FIG.1b

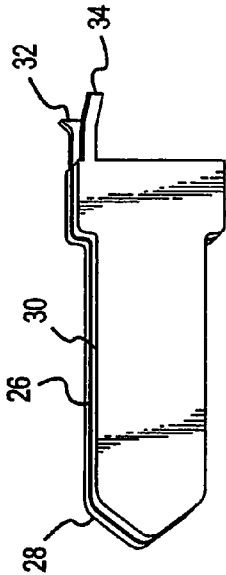


FIG. 2a

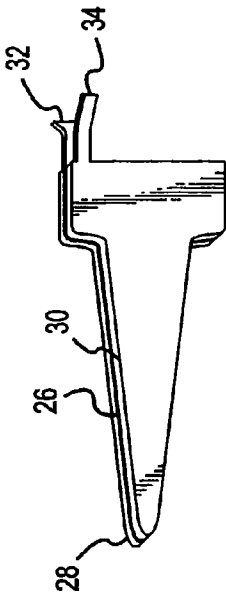


FIG. 2b

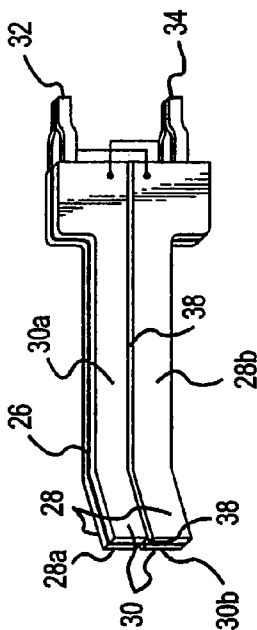


FIG. 2c

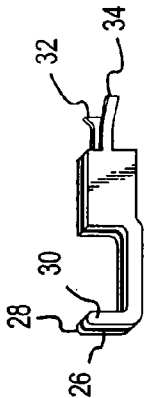


FIG. 2d

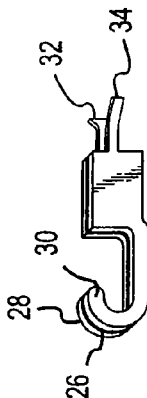


FIG. 2e

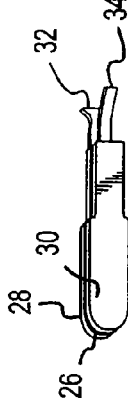


FIG. 2f

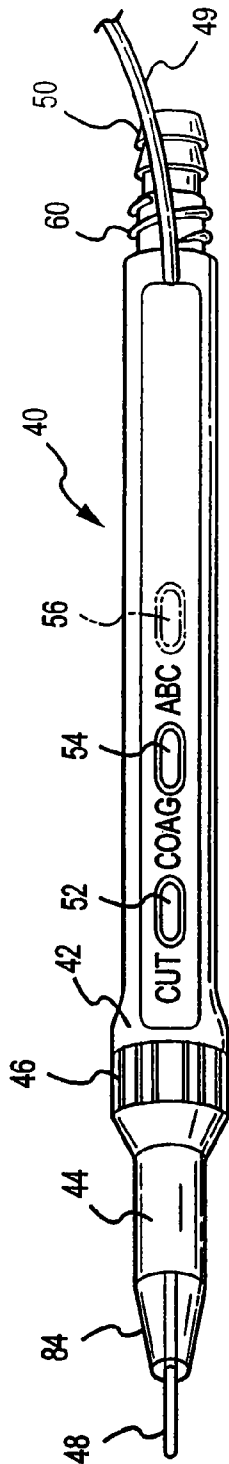


FIG. 3a

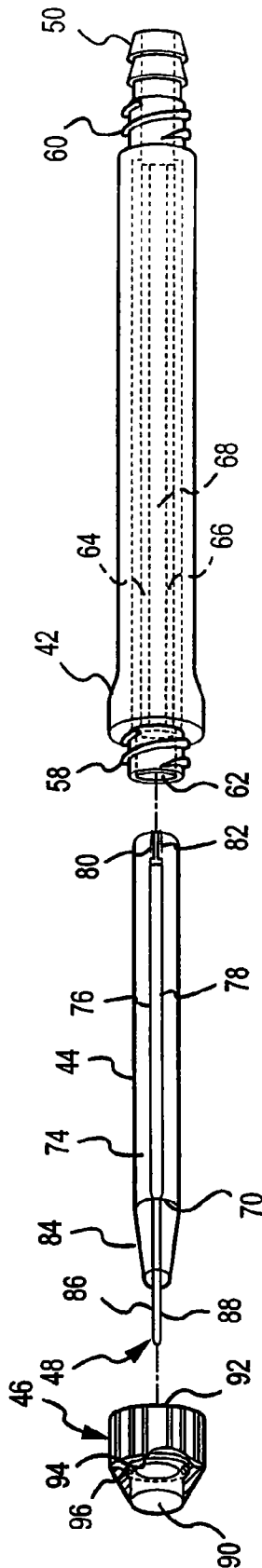


FIG. 3b

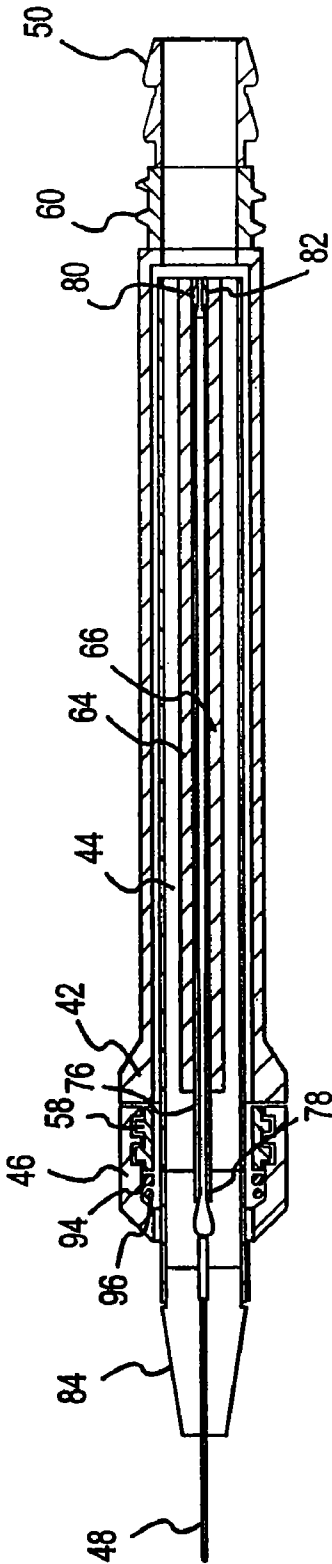


FIG. 3c

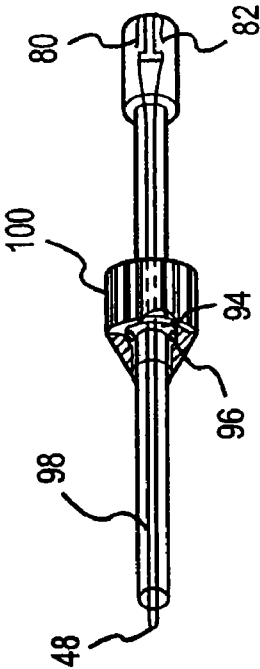


FIG. 3d

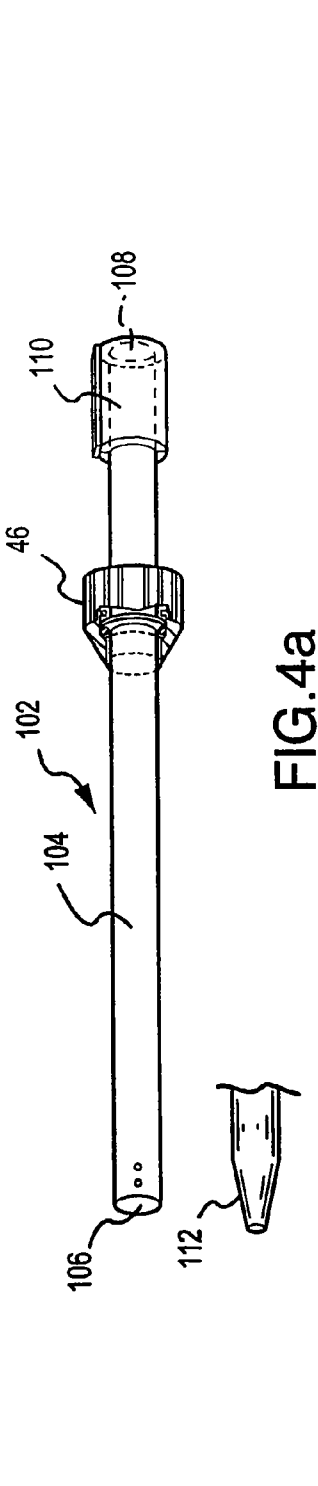


FIG. 4a

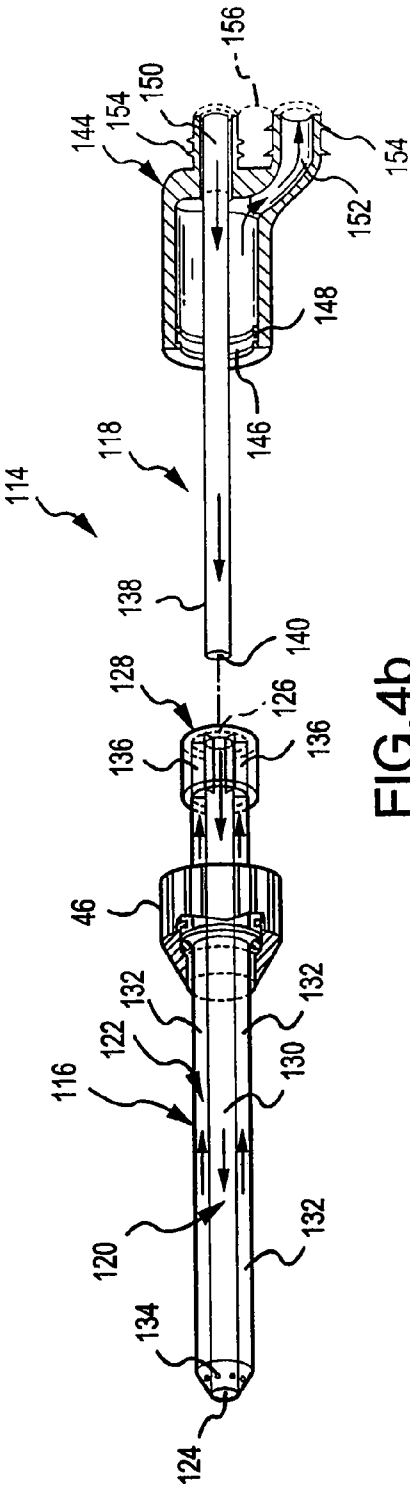


FIG. 4b

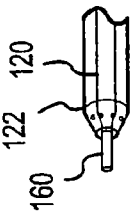


FIG. 4c

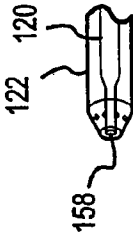
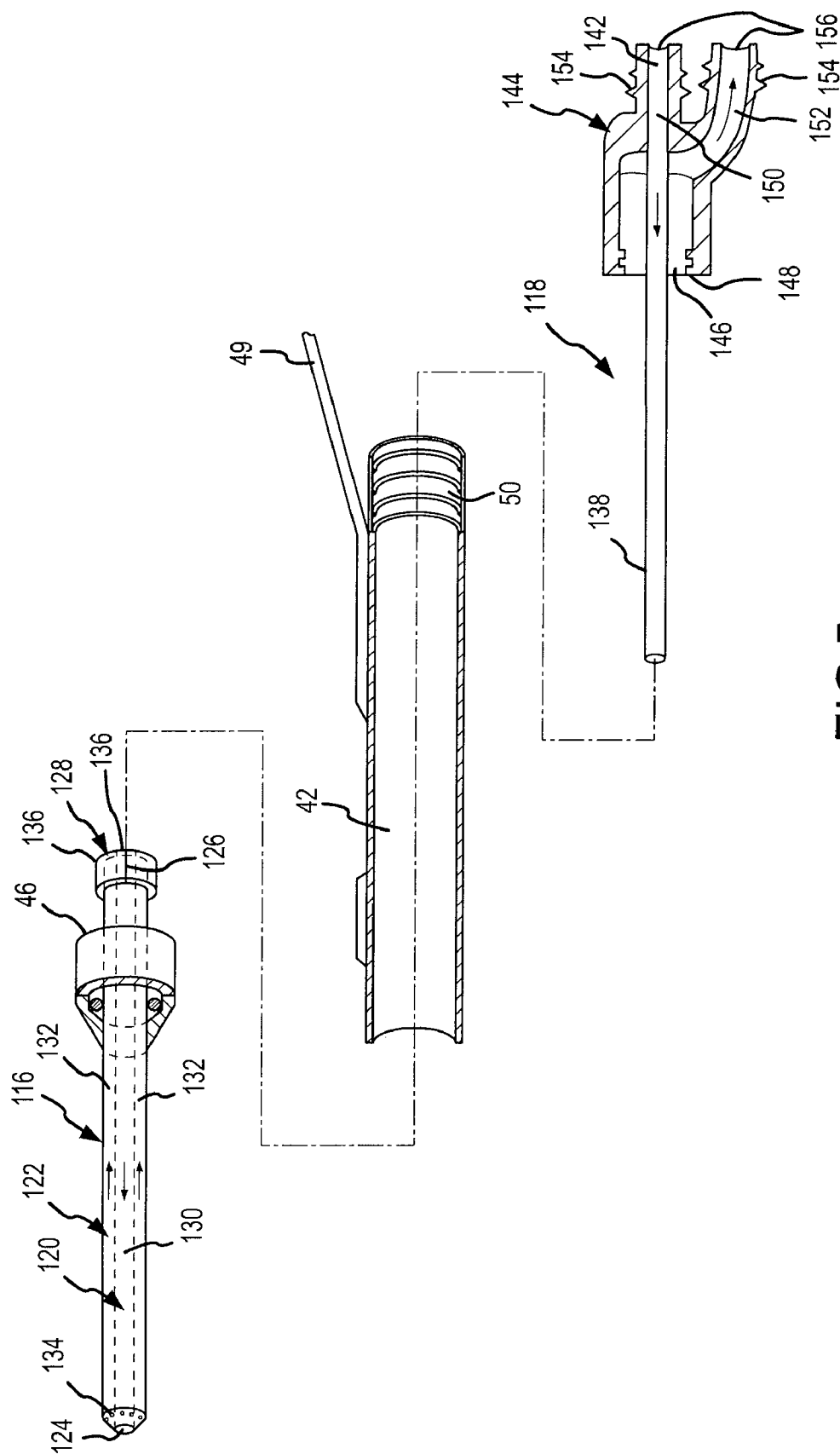


FIG. 4d



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MULTIFUNCTIONAL TELESCOPIC MONOPOLAR/BIPOLAR SURGICAL DEVICE AND METHOD THEREOF

CROSS REFERENCE TO RELATED APPLICATIONS

This application is a continuation of and claims benefit of priority to U.S. Nonprovisional patent application Ser. No. 10/796,748 filed Mar. 8, 2004, now U.S. Pat. No. 7,112,199, which is a continuation-in-part of patent application Ser. No. 09/977,408 filed Oct. 15, 2001, now U.S. Pat. No. 6,702,812, which was a continuation of patent application Ser. No. 09/088,386 filed Jun. 1, 1998, now U.S. Pat. No. 6,355,034, which was a continuation of patent application Ser. No. 08/717,494 filed Sep. 20, 1996, now abandoned, which applications are hereby incorporated by reference in their entirety.

FIELD OF INVENTION

The present invention relates generally to an electrosurgical unit (ESU) pencil. More specifically, the present invention relates to an ESU pencil having a bipolar electrode wherein the active and return electrode are contained within the same tip of the ESU pencil and are separated by a high temperature resistant radio frequency (RF) dielectric. The ESU pencil having a bipolar electrode is designed for use with a monopolar ESU device in a bipolar function for cutting and coagulation in medical procedures. When used with a monopolar ESU device, the ESU pencil having a bipolar electrode can also be used for monopolar application wherein a separate electrode is applied to a part of the patient's body, usually on the patient's leg, to function as the return electrode. This monopolar function is prevalent in the prior art.

The present invention also relates to a telescopic laparoscopic monopolar/bipolar ESU pencil having an adjustable length electrode capable of accommodating different depths and/or different sizes of adult and children. The telescopic laparoscopic monopolar/bipolar ESU pencil can also be used with an integrated smoke evacuator system such as that previously described in U.S. Pat. No. 5,199,944. Also, the ESU pencil of the present invention having a bipolar electrode may be combined with the suction/irrigation system and apparatus previously described in my co-pending patent application entitled "Automatic Suction/Irrigation Apparatus for Use in Laparoscopic Surgery and Electrosurgery and Method Therefor" which is being simultaneously filed with the present application and is incorporated by reference thereto. Finally, the ESU pencil of the present invention having a bipolar electrode can be combined with attachments so that it can also be used for argon beam coagulation.

BACKGROUND OF THE INVENTION

In the past, electrosurgical devices had an active electrode that was used for performing cutting and coagulation, and a return electrode which usually comprised an adhesive for attachment to a patient's skin. When the electrosurgery unit surgery pencil was activated, the RF energy circulated from the active electrode to the return electrode through the patient's body with the distances between the active and return electrodes being fairly significant.

This prior art system presents several deficiencies and creates, a number of problems that can be dangerous for the patient. First, because of the significant distance between the active and return electrodes, high voltages at high frequencies are transversed through the body in order to close the circuit

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between the active and return electrodes. These high voltages and frequencies can be very dangerous to the patient. Second, due to the fact that the body has an electrical resistance, the cutting and coagulation affects are significantly diminished as the distance between the active and return electrodes is increased. Accordingly, high power from the ESU is needed in order to obtain effective cutting and coagulation performance. Again, the high power required from the ESU can be dangerous to the patient.

Third, in many cases, patients have incurred significant burns because of poor contact between the return electrode and the patient's skin. Finally, dangerous capacitive coupling has occurred in laparoscopic surgery which has resulted in dangerous burns to the patient. These burns could not be detected because they are out of the field of view of the laparoscope thereby putting the patient's life in danger.

A bipolar function for open and laparoscopic procedures is presently being used with the bipolar suction of the ESU. However, this system and the related instruments are used only to stop bleeding within a patient and is not capable of performing a cutting operation.

As previously stated in the section referred to as "related application", the present invention is related to the same inventor's pending patent application entitled "Telescopic Surgical Device and Method Therefor". The similarities between the telescopic pencil described in the pending application and the present invention described in this application is that both inventions refer to a telescopic pencil which can have multifunctional applications. The main difference between the inventions is that the pending telescopic pencil patent application refers to a monopolar pencil only which has only one contact for the electrode while the ESU pencil of the present invention described in this application can be used as a monopolar instrument, a monopolar/bipolar instrument or a bipolar instrument. The ESU pencil of the present invention has an electrode which comprises two contacts, one which is used as an active electrode and another which is used as a return electrode when the instrument is used as a bipolar functioning instrument for a monopolar/bipolar functioning instrument. Alternatively, when the instrument is only used as a monopolar functioning instruments a separate electrode is applied to a different part of the patient's body, usually on the patient's leg. This separate electrode functions as the return electrode.

SUMMARY OF THE INVENTION

A principal object of the present invention an electrosurgery electrode for performing cutting and coagulation for open and closed endoscopic and laparoscopic procedures wherein the electrosurgery electrode contains both the active electrode and the return electrode on the same tip.

It is a further objection of the present invention to provide a monopolar/bipolar electrode which can be used on the monopolar section of an electrosurgery unit to perform a bipolar function thereby eliminating the need for a separate return electrode.

It is still a further object of the present invention to provide a telescopic monopolar and monopolar/bipolar electrode and pencil with smoke evacuation means wherein the distance between the operating tip of the electrode and the hand piece is adjustable to accommodate desired lengths associated with different sized patients.

It is yet a further object of the present invention to provide a telescopic monopolar and monopolar/bipolar endoscopic

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and laparoscopic electrode, with or without smoke evacuation means, wherein the length of the laparoscopic electrode is adjustable.

It is still a further objection of the present invention to provide a telescopic monopolar and monopolar/bipolar ESU pencil with suction/irrigation means wherein the bipolar electrode is automatically retracted upon activation of the suctioning means.

It is still a further object of the present invention to provide a telescopic monopolar and monopolar/bipolar electrode and pencil for open and closed endoscopic and laparoscopic procedures with suction/irrigation means wherein the electrode can be automatically retracted upon the activation of the suctioning means.

It is yet a further object of the present invention to provide a multi-functional telescopic ESU pencil that can be used for open and laparoscopic electrosurgery that is also capable of performing suction and irrigation, and for argon beam coagulation when used with respective attachments as previously described in reference to my pending U.S. Patent Application entitled "Telescopic Surgical Device and Method Therefor".

Accordingly, the multi-functional telescopic monopolar/bipolar surgical device of the present invention includes a bipolar electrode and a hand piece having electrical contacts wherein the bipolar electrode is connected to the electrical contacts of the hand piece and the electrical contacts of the hand piece are connected to an energy source for activating the device. An electrosurgery unit may be used as the energy source. The bipolar electrode includes an active electrode, a return electrode and an insulator which is sandwiched between the active and return electrodes. The multi-functional telescopic monopolar/bipolar surgical device may further include a telescopic member coupled to the bipolar electrode and the hand piece for adjusting the length of the bipolar electrode. Further, the multi-functional telescopic monopolar/bipolar surgical device may include a smoke evacuation means coupled to the bipolar electrode for removing smoke and other debris that is produced during electrosurgery.

The present invention is also directed to a telescopic suction/irrigation apparatus for open and endoscopic laparoscopic procedures which includes a hollow hand piece member having an open distal end and an open proximal end and connection means for connecting the hand piece to an energy source for activating suction and irrigation, an elongated hollow tubular member having distal and proximal open ends wherein the distal open end is introduced into the open proximal end of the hand piece so that the elongated hollow tubular members are concentrically contained within the channel of the hand piece, and locking means for locking the elongated hollow tubular member within the hand piece. Another embodiment of the telescopic suction/irrigation apparatus comprises a hand piece member having connection means to an energy source and means for effectuating suction and irrigation functions, a double channel telescopic suction/irrigation tube having an inner channel and outer channel wherein the double channel telescopic suction/irrigation tube is introduced into the hand piece member such that a portion of the double channel telescopic suction/irrigation tube is concentrically retained within the hand piece, connection means for connecting the inner channel of said double channel telescopic suction/irrigation tube with an irrigation port and the outer channel of the double channel telescopic suction/irrigation tube with a suctioning port, and locking means for locking the double channel telescopic suction/irrigation tube within the hand piece member.

The present invention is also directed to a method for performing electrosurgery on a patient which comprises the

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steps of connecting a bipolar electrode having an active electrode and a return electrode to a hand piece with means for alternately effectuating cutting and coagulation with the bipolar electrode, connecting both the active and return electrodes to an energy source, and activating either the cutting or coagulation function using the bipolar electrode.

The foregoing and other objections, features and advantages of the present invention, as well as details of the preferred embodiments thereof, will be more fully understood from the following descriptions made in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1a is a diagrammatic view of electrosurgery being performed on a patient using a prior art ESU pencil having a monopolar electrode which requires a separate return electrode.

FIG. 1b is a diagrammatic view of electrosurgery being performed on a patient using the telescopic monopolar/bipolar surgical device of the present invention for electrosurgery.

FIG. 2a is a perspective view of a first embodiment of a bipolar electrode for use within the telescopic monopolar/bipolar surgical device of the present invention for electrosurgery which can also function as a monopolar electrode.

FIG. 2b is a perspective view of a second embodiment of a bipolar electrode for use within the telescopic monopolar/bipolar surgical device of the present invention for electrosurgery which can also function as a monopolar electrode.

FIG. 2c is a perspective view of a third embodiment of a bipolar electrode for use within the telescopic monopolar/bipolar surgical device of the present invention for electrosurgery which can also function as a monopolar electrode.

FIG. 2d is a perspective of a first embodiment of a bipolar electrode used in the multifunctional telescopic monopolar/bipolar surgical device of the present invention for endoscopic and/or laparoscopic procedures wherein the bipolar electrode is capable of a monopolar function.

FIG. 2e is a perspective view of a second embodiment of a bipolar electrode used in the multifunctional telescopic monopolar/bipolar surgical device of the present invention for endoscopic and/or laparoscopic procedures wherein the bipolar electrode is capable of a monopolar function.

FIG. 2f is a perspective view of a third embodiment of a bipolar electrode used in the multifunctional telescopic monopolar/bipolar surgical device of the present invention for endoscopic and/or laparoscopic procedures wherein the bipolar electrode is capable of a monopolar function.

FIG. 3a is a perspective view of the multi-functional monopolar/bipolar telescopic electrosurgical device of the present invention.

FIG. 3b is a perspective exploded view of the device in FIG. 1 shown without the electrical cord.

FIG. 3c is cross-sectional view of the device in FIG. 3A shown without the electrical cord.

FIG. 3d is a perspective view of an endoscopic and/or laparoscopic telescope element which can replace the telescopic element of the multi-functional monopolar/bipolar telescopic electrosurgical device shown in FIG. 3C to create a multi-functional monopolar/bipolar telescopic electrosurgical device for endoscopic and/or laparoscopic procedures.

FIG. 4a is a perspective view of a suction/irrigation telescope which can replace the electrosurgery telescope in FIG. 3C or the laparoscopic telescope in FIG. 3D to provide a telescopic surgical device with suction/irrigation means capable of performing either suction or irrigation.

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FIG. 4b is a perspective exploded view and partial cross-sectional view of a second embodiment of a suction/irrigation telescope which can replace the electrosurgery telescope in FIG. 3C or the laparoscopic telescope in FIG. 3D to provide a telescopic device with suction/irrigation means capable of performing suction and irrigation simultaneously.

FIG. 4c is a partial cross sectional view of a hydro dissection nozzle wherein the internal tube of the nozzle is shown retracted.

FIG. 4d is a partial cross sectional view of the hydro dissection nozzle shown in FIG. 4c with the internal tube shown extended.

FIG. 5 is a perspective exploded view of one embodiment of the telescopic suction/irrigation apparatus of the present invention.

DETAILED DESCRIPTION

The present system for performing electrosurgery with an ESU pencil having a monopolar electrode is shown in FIG. 1a. The electrosurgery pencil 10 comprises an active electrode 12 which performs cutting or coagulation on a patient 14. The ESU pencil 10 comprising active electrode 12 is connected to the electrosurgery unit 16 which provides the energy source to activate the ESU pencil 10. A return electrode 18 comprises an adhesive patch 20 which is positioned and applied to the patient 14 at a considerable distance 22 away from the active electrode 12. The return electrode 18 is also connected to the electrosurgery unit 16 thereby creating a close circuit wherein the voltage and frequency emitted from the active electrode 12 is transmitted through the body of the patient 14 and received by return electrode 20. FIG. 1a illustrates how monopolar electrosurgery is presently performed.

Electrosurgery performed on a patient using the multifunctional telescopic monopolar/bipolar surgical device of the present invention is shown in FIG. 1b. With the present invention, the electrosurgery pencil 10 comprises a bipolar electrode 11 which comprises an active electrode 12 and a return electrode 18 which are separated by a material dielectric 13 which functions as an insulator. Both the active electrode 12 and the return electrode 18 are connected to the electrosurgery unit 16 thereby performing a completed circuit. When the electrosurgery unit 16 is activated and the bipolar electrode 11 touches the tissue of the patient 14, the circuit is closed through a very small portion of the patient's tissue between the active electrode 12 and the return electrode 18. This shortened distance between the active electrode 12 and return electrode 18 results in decrease of the power requirement from that previously needed in association with the monopolar electrode of the prior art in order to effectuate cutting and coagulation. This decreased distance between the two electrodes 12, 18 also results in decreasing the dangers associated with passing high voltages at high frequencies throughout a substantial portion of the patient's body, one of those risks being an increased possibility of burns to the patient.

FIGS. 2a-c show perspective views of different embodiments of bipolar electrodes which comprise part of the multifunctional telescopic monopolar/bipolar surgical device of the present invention for open electrosurgery procedures. These electrodes are capable of exhibiting both bipolar and monopolar functioning in conjunction with an electrosurgery unit.

FIG. 2a represents a perspective view of a bipolar blade electrode. An insulator 26 is sandwiched between the active electrode 28 and the return electrode 30. Active electrode 28

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further comprises an active prong 32 which is designed to come in contact with an active conductor contained within the telescopic element of the device of the present invention which is shown and described later with reference to FIGS. 3b and 3c. Further, the return electrode 30 comprises a return prong 34 which is designed to make contact with a return conductor contained within the telescopic element of the device of the present invention which is also shown and described later with reference to FIGS. 3b-3c.

FIG. 2b represents a perspective view of a bipolar needle electrode. Again, an insulator 26 is sandwiched between the active electrode 28 and the return electrode 30 wherein the active electrode 28 and return electrode 30 further comprise an active prong 32 and return prong 34, respectively, for connection to conductor elements contained within a telescopic element of a device of the present invention as shown in FIGS. 3b-3c.

FIG. 2c represents a perspective view of a special angled bipolar electrode that can be used for cutting and/or coagulation, as well as for surface coagulation or ablation. An insulator 26 is sandwiched between active and return electrodes wherein one of each of an active electrode 28 and a return electrode 30 are positioned on opposite sides of the insulator 26. More specifically, on a first side (not shown) of insulator 26 there is a top active electrode 28A and a bottom return electrode 30B and on a second side 38 of insulator 26 there is a top return electrode 30A and a bottom active electrode 28B. Active prong 32 connects top active electrode 28A to bottom active electrode 28B while return prong 34 serves to connect top return electrode 30A to bottom return electrode 30B thereby forming connection means for the active electrode 28 and return electrode 30, respectively, when connecting the active and return electrodes 28, 30 to conductors contained within the telescopic elements of the device of the present invention as further explained with reference to FIGS. 3b-3c. The previously described electrodes may further vary by comprising a variety of different shapes without detracting from the purpose of the invention.

FIGS. 2d-2f depict perspective views of bipolar electrodes which comprise part of the multifunctional telescopic monopolar/bipolar surgical device of the present invention for performing endoscopic and/or laparoscopic procedures wherein the electrode is also capable of monopolar functioning alone. FIGS. 2d and 2e represent hook-shaped bipolar electrodes for use in endoscopic and laparoscopic procedures wherein the bipolar electrodes are also capable of functioning as monopolar electrodes. FIG. 2f shows a paddle-shaped bipolar electrode for use in endoscopic and/or laparoscopic procedures which may also function as a monopolar electrode. All of the bipolar electrodes depicted in FIGS. 2d-2f comprise an insulator 26 which is sandwiched between an active electrode 28 and a return electrode 30. Further, the active electrode 28 comprises an active prong 32 while the return electrode 30 comprises a return prong 34 wherein both the active prong 32 and return prong 34 serve as connection means for connecting the active electrode 28 and return electrode 30 to conductors contained within a laparoscopic/endoscopic telescope element of the device of the present invention as further detailed in reference to FIG. 3d.

Other electrode shapes and forms may be used with respect to the bipolar electrodes for endoscopic and/or laparoscopic procedures without detracting from the purpose of the invention. Further, the active electrode 28 and return electrode 30 on all of the previously described bipolar electrodes in reference to FIGS. 2a-2f may be reversed such that the active

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electrode **28** and return electrode **30** are on opposite sides of the insulator **26** than those on which they are depicted in the Figures.

Active electrode **28** is preferably comprised of stainless steel or other suitable conductors and return electrode **30** is preferably comprised of a ceramic or other suitable material which can function as an insulator. The insulator **26** is preferably comprised of a dielectric material which is suitable for use as a dielectric in radio frequency applications and at very high temperatures such as certain types of ceramics. However, any dielectric materials that can meet the conditions for RF applications at very high temperatures may be used.

As previously explained with reference to FIG. 1B, the circuit created by the active electrode **28** and return electrode **30** is closed when the ESU is activated and the electrode touches the tissue of a patient. This very small portion of the patient's tissue closes the gap between the active electrode **28** and the return electrode **30**. As a result, much less power is needed to traverse the patient's tissue in order to close the circuit and effectuate the cutting and coagulation operations. A load resistor can be installed in series to avoid an accidental short circuit in between the two electrodes.

Turning now to FIG. 3a, there is shown a perspective view of the multi-functional telescopic monopolar/bipolar electro-surgical device of the present invention. In brief, the multi-functional telescopic monopolar/bipolar electrosurgical device **40** of the present invention comprises a main body **42**, a telescopic body **44** circumferentially contained within the main body **42** such that it can be extended outward from, and retracted into, the main body **42**, a locking element **46** which locks the telescopic body **44** to the main body **42** at a predetermined extracted length, a bipolar electrode **48** contained within the telescopic body and main body such that it is capable of being in electrical contact with an electrosurgery unit, and a connector element **50** for connecting the main body **42** of the device **40** to a smoke evacuator tubing (not shown). The main body **42** of the device **40** further comprises a series of selection buttons, one selection button for cutting **52**, one selection button for coagulation **54**, and one selection button for argon beam coagulation **56**. The selection button for argon beam coagulation is optional. The main body may be provided with only cutting and coagulation selection buttons **52**, **54**.

An exploded view of the multifunctional telescopic monopolar/bipolar electrosurgical device **40** of the present invention is illustrated in FIG. 3b. The main body **42** of the device **40** comprises a distal thread **58** and a proximal thread **60** which are connected by a channel **62**. The main body **42** further comprises an active contact **64** and a return contact **66** which are located parallel to one another on an interior surface of the channel **62** having a gap located there between which resembles an elongated slot **68**. The telescopic body **44** comprises a distal end **70** and a proximal end **72** which are separated by a second channel **74** that is smaller in diameter than the channel **62** contained within the main body **42**. The telescopic body **44** further comprises a pair of elongated conductors **76**, **78** located within the second channel **74** of the telescopic body **44**. Each of the elongated conductors **76**, **78** terminate in contact prongs **80**, **82**, respectively, such that the contact prongs **80**, **82** are located on the external surface of the telescopic body **44** near its proximal end **72**. A hollow nozzle **84** may be connected to the distal end **70** of the telescopic body **44**.

The bipolar electrode **48** is connected to the telescopic body **44** such that the active electrode **86** and return electrode **88** are in contact with the elongated conductors **76**, **78**, respectively. Finally, the locking element **46** comprises a

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hollow interior having a distal end **90** and a proximal end **92**. The locking element **46** further comprises a ridge **94** contained within its hollow interior and an "O" ring **96** which is seated on the ridge **94**. As a result, the locking element **46** can be slid over the telescopic body **44** and connected to the distal thread **58** of the main body **42** to enable the telescopic body **44** to be locked in position within the main body **42**.

FIG. 3c shows a cross sectional view of the multifunctional telescopic monopolar/bipolar electrosurgery unit pencil shown in FIG. 3a. As previously described, the main body **42** contains active contact **64** and patient return contact **66** which are parallel to one another so that they are separated by the same distance along their entire lengths. Contact prongs **80**, **82** contained on the external surface of the telescopic body **44** are slightly engaged and maintained within the elongated slot **68** which separates the active contact **64** from the patient return contact **66**. The bipolar electrode **48** is connected to the contact prongs **80**, **82** via the elongated conductors **76**, **78**. The telescopic body **44** is extracted or retracted within the main body **42** to adjust for the desired length of the bipolar electrode **48**.

Argon beam coagulation attachments (not shown) replace the telescopic body **44** described above with a special telescope and end attachment similar to those described in my previous patent application entitled "A Telescopic Surgical Device and Method Therefor" may be attached to the proximal thread **60** of the main body **42** of the device **40**. A suction/irrigation attachment such as that later described and shown in FIGS. 4a-4b, as well as a connector for smoke evacuation tubing (not shown) may also be connected to proximal thread **60** of the main body **42** of the device **40**. The locking element **46** is threaded onto the distal thread **58** of the main body **42** of the device **40** in order to lock the telescopic body **44** in place. The telescopic body **44** is locked in position by tightening the locking element **46** against the distal thread **58** of the main body **42**. As a result, the ridge **94** contained within the locking element **46** is pushed forward such that it presses over the "O" ring **96** which in turn presses over the telescopic body **44** thereby locking it in place.

During use, when either the cutting button **52** or the coagulation button **54** is depressed, the active contact **64** is energized and the return contact **66** acts to return current from the patient to the electrosurgery unit. Contact prongs **80**, **82** function to pass the radio frequency energy through elongated conductor **76** to the bipolar electrode **48** and then return the RF energy through elongated conductor **78** back to contact prong **82**. If the multifunctional telescopic monopolar/bipolar surgical pencil device of the present invention is used for monopolar only, then the active contact **64** and return contact **66** will both conduct the active energy and a separate return electrode will be provided and utilized as represented in FIG. 1A. Energy is brought to the multifunctional telescopic monopolar/bipolar surgical pencil device of the present invention by electrical cord **49** (See FIG. 3a) which is connected to an electrosurgery unit (not shown).

Turning now to FIG. 3d, there is shown an endoscopic/laparoscopic telescopic body **98** which replaces the telescopic body **44** shown in FIGS. 3b-3c in order to perform endoscopic and/or laparoscopic procedures. The second locking element **100** works similar to the locking element **46** described with reference to FIGS. 3b-3c. The cutting operation is activated when the cutting button **52** is depressed and coagulation is activated when the coagulation button **54** is depressed. Argon beam coagulation button number **56** is optional and, if used, the endoscopic/laparoscopic telescope body **98** is replaced with a different telescope such as that described in my pending patent application entitled "A Tele-

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scopic Surgical Device and Method Therefor" and an adaptor is attached to the end of the device **40** at the proximal thread **60** of the main body **42** of the device **40**. The adaptor is very similar to the adaptor for suction/irrigation that is later shown and described with reference to FIG. **4**.

FIGS. **4a-4c** show another embodiment of the electrosurgery pencil of the present invention which is directed toward a telescopic suction/irrigation pencil for electrosurgery. The telescopic monopolar/bipolar surgical pencil depicted and described in FIGS. **3a-3d** will become a telescopic suction/irrigation pencil by replacing the telescopic body **44** in FIGS. **3b-3c** and the endoscopic/laparoscopic telescopic body **98** in FIG. **3d** with the attachments presented in FIGS. **4a-4b**. The resulting telescopic suction/irrigation pencil is advantageous in that it permits the surgeon to adjust the lengths of the suction/irrigation tip without the need for removing and reattaching tips of different lengths.

FIG. **4a** shows a perspective view of a first embodiment of a suction/irrigation attachment **102** comprising a singular hollow tube **104** having a distal end **106** and a proximal end **108**. The suction/irrigation attachment **102** further comprises a sliding guide **110** which is circumferentially fit about the proximal end **108** of the singular hollow tube **104** thereby allowing the suction/irrigation attachment **102** to be slidably engaged within the main body **42** of the telescopic monopolar/bipolar electrosurgery device **40** shown in FIG. **3b**. The locking element **46** shown in FIG. **3b** is also used in conjunction with the suction/irrigation attachment **102** shown in FIG. **4a** in order to lock the suction/irrigation attachment **102** in place at a predetermined extracted length from the main body **42** shown in FIG. **3b**. The resulting device is a telescopic suction/irrigation pencil for use with electrosurgery as well as laparoscopic and endoscopic procedures.

Suction and irrigation are activated by using the cutting button **52** shown in FIG. **3a** for irrigation and the coagulation button **54** shown in FIG. **3a** for suction. During irrigation, the irrigation fluid enters the telescopic suction/irrigation pencil through connector element **50**, then passes through the proximal end **108** of the singular hollow tube **104** shown in FIG. **4a** and then exits the telescopic suction/irrigation pencil through the distal end **106** of the singular hollow tube **104** shown in FIG. **4a**. In contrast, when suction is activated, fluid is drawn from the patient and enters the telescopic suction/irrigation pencil at the distal end **106** of the singular hollow tube **104**, is further drawn past the proximal end **108** of the singular hollow tube **104**, and finally exits the telescopic suction/irrigation pencil through the connector element **50** shown in FIG. **3b**.

The distal end **106** of the suction/irrigation attachment **102** may be narrowed to form a nozzle **112** such as that shown in FIG. **4a**. The nozzle **112** configuration of the distal end **106** facilitates the use of the telescopic suction/irrigation pencil for hydra-dissection by enabling the irrigation fluid to exit the distal end **106** of the suction/irrigation attachment **102** with high pressure and velocity.

FIG. **4b** illustrates an exploded perspective view of a second embodiment of a suction/irrigation attachment **114** which is capable of performing suction and irrigation simultaneously. The lengths of the telescopic suction and irrigation tubes may also be adjusted. The second embodiment of the suction/irrigation attachment **114** comprises a double channelled tube **116** and a singular connection tube **118**. The double channelled tube **116** comprises a first hollow tube **120** circumferentially contained within a second hollow tube **122** wherein the first and second hollow tubes **120**, **122** are of substantially the same length. The double channelled tube **116** further includes a distal end **124**, a proximal end **126**, a spacer

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element **128** located at the proximal end **126** of the double channelled tube **116**, and a locking element **46** which functions like the locking element **46** shown and described with reference to FIG. **3b**.

The double channelled tube **116** contains a central inner channel **130** which is defined by the hollow inner area of the first hollow tube **120** and an outer ring-shaped channel **132** which is defined by the opening generated by the difference between the inner diameter of the second hollow tube **122** and the outer diameter of the inner hollow tube **120**. Irrigation is conducted through the central inner channel **130** while suction is conducted through the outer ring-shaped channel **132**.

The second hollow tube **122** is closed about the first hollow tube **120** at the distal end **124** of the double channelled tube **116** but a plurality of apertures **134** are contained about the circumference of the second hollow tube **122** near distal end **124** thereby creating an opening through which fluid can pass through the outer ring-shaped channel **132**. The spacer element **128** comprises a shortened hollow cylinder having a proximal open end and a plurality of wings **136** located within its opposite open end. The plurality of wings **136** are positioned within the outer ring-shaped channel **132** located between the first hollow tube **120** and the second hollow tube **122** to maintain the distance between the tubes **120**, **122** and support the outer ring-shaped channel **132** while still allowing irrigation fluid to pass through the outer ring-shaped channel **132** with minimal resistance.

The singular connection tube **118** comprises a tube **138** having an open distal end **140** and an open proximal end **142** wherein the open proximal end **142** is seated within a multi-connector piece **144**. Multi-connector piece **144** comprises a hollow piece having a large open distal end **146** with grooves **148** for receiving threads and two smaller channels **150**, **152** each having threads **154** located at its proximal end **156**. Threaded channel **150** is designed to be attached to an irrigation means while threaded channel **152** is designed for attachment to a suctioning means.

During use, the grooves **148** at the large open distal end **146** of the multi-connector piece **144** are connected to the proximal thread **60** of the main body **42** of the device **40** shown in FIG. **3b** while the tube **138** is inserted through the channel **62** of the main body **42** such that tube **138** will exit the channel **62** and enter the central inner channel **130** of the first hollow tube **120** of the double channelled tube **116** when the spacer element **128** is slid within the main body **42** of the device **40** shown in FIG. **3b**. Tube **138** has an outer diameter that is slightly smaller than the inner diameter of the first hollow tube **120** so that hollow tube **120** and tube **138** form a telescope when concentrically enjoined.

When irrigation is activated, irrigation fluid will be introduced under pressure through the open proximal end **142** of tube **138** and will traverse the telescopic configuration resulting from joining tube **138** inside of first hollow tube **120**, and will then exit at the distal end **124** of the double channelled tube **116** through the first hollow tube **120**. When suction is activated, suctioning means is applied at suctioning channel **152** and fluid is drawn from the patient through the plurality of apertures **134** contained within the second hollow tube **122**. The fluid is drawn through the ring-shaped outer channel **132** and then exits at the suctioning channel **152**. Spacer element **128** slides within the main body **42** of the device **40** shown in FIG. **3b** and the second hollow tube **122** is locked into place by connecting locking element **46** to distal thread **58** of the main body **42** of the device **40**.

The distal end **124** of the double channelled tube **116** of the suction/irrigation attachment shown in FIG. **4b** may comprise an alternative configuration such as that shown in FIGS.

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4c-4d. FIGS. 4c-4d depict a nozzle configuration in which the distal open end **158** of first hollow tube **120** forms a needle nose **160** which is capable of being extracted and retracted from within the second hollow tube **122** thereby allowing the operator or surgeon to adjust the length of the irrigation means such that it extends beyond the length of the suctioning means at the cite of application.

While the invention has been particularly shown and described with reference to the preferred embodiments thereof, it will be understood by those skilled in the art that changes in form and detail of the foregoing may be made without departing from the spirit and scope of the present invention. For example, if a different shape or form is given to the monopolar/bipolar electrodes but they are still capable of functioning with a monopolar ESU suction to provide a bipolar function, this new configuration is believed to be included within the scope of the present invention. Further, different locking means for locking the telescopic functioning elements in place as well as different configurations for providing electrical contact means within the telescopic body and main body of the device are believed to be included within the spirit and scope of the present invention.

The invention claimed is:

1. A multifunctional electrosurgery pencil for use with an energy source comprising:

an electrode;

a handpiece with means for connecting said electrode to said energy source;

telescopic member means contained within said handpiece for adjusting the length of said telescopic member means extending from said handpiece wherein at least a portion of said electrode is contained within said telescopic member means; and

smoke evacuation means coupled to said handpiece for removing smoke and debris produced during a medical procedure using said electrosurgery pencil and energy source.

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2. The multifunctional electrosurgery pencil of claim 1 wherein said energy source is an electrosurgery unit.

3. The multifunctional electrosurgery pencil of claim 1 further comprising means for effectuating at least one of alternate and simultaneous suction and irrigation functions.

4. The multifunctional electrosurgery pencil of claim 3 wherein said energy source is an electrosurgery unit.

5. The multifunctional electrosurgery pencil of claim 1 wherein said electrode is a bipolar electrode.

6. A multifunctional telescopic electrosurgery pencil for use with an energy source comprising:

a main body having a first end and a second end in continuous communication with one another wherein the second end is capable of being coupled to smoke evacuation means for removing smoke and debris produced during a medical procedure using said electrosurgery pencil and energy source;

a movable telescopic body circumferentially contained within the first end of the main body; and

an electrode contained within at least a portion of the movable telescopic body such that it is capable of being in electrical contact with the energy source.

7. The multifunctional telescopic electrosurgery pencil of claim 6 wherein said energy source is an electrosurgery unit.

8. The multifunctional telescopic electrosurgery pencil of claim 6 further comprising means for effectuating at least one of alternate and simultaneous suction and irrigation functions.

9. The multifunctional telescopic electrosurgery pencil of claim 8 wherein said energy source is an electrosurgery unit.

10. The multifunctional telescopic electrosurgery pencil of claim 6 wherein said electrode is a bipolar electrode.

* * * * *

EXHIBIT B

US008414576B2

(12) **United States Patent**
Cosmescu(10) **Patent No.:** **US 8,414,576 B2**
(45) **Date of Patent:** **Apr. 9, 2013**(54) **SWIVEL DEVICE FOR ELECTROSURGERY
PENCIL AND SURGICAL SMOKE
EVACUATION**(76) Inventor: **Ioan Cosmescu**, Phoenix, AZ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 992 days.

(21) Appl. No.: **12/137,788**(22) Filed: **Jun. 12, 2008**(65) **Prior Publication Data**

US 2009/0018539 A1 Jan. 15, 2009

Related U.S. Application Data

(63) Continuation-in-part of application No. 11/164,712, filed on Dec. 2, 2005.

(51) **Int. Cl.**
A61B 18/18 (2006.01)
A61B 18/04 (2006.01)(52) **U.S. Cl.**
USPC **606/41**; 606/28; 606/32; 606/49(58) **Field of Classification Search** 604/19-22,
604/902, 27-52; 606/27-52
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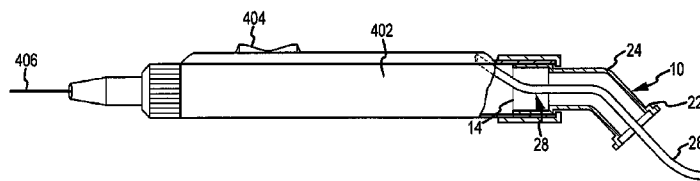
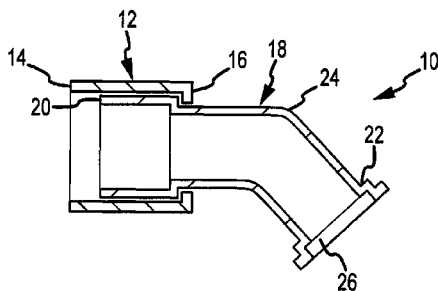
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Primary Examiner — Nicholas Lucchesi*Assistant Examiner* — Leah Stohr(74) *Attorney, Agent, or Firm* — Zeman—Mullen & Ford, LLP(57) **ABSTRACT**

A swivel device for connection to an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment includes a fixed member attached to a rotating member. The rotating member allows an electrical cord and/or vacuum tube to twist and coil freely during operation of an ESU pencil with or without the smoke evacuation system.

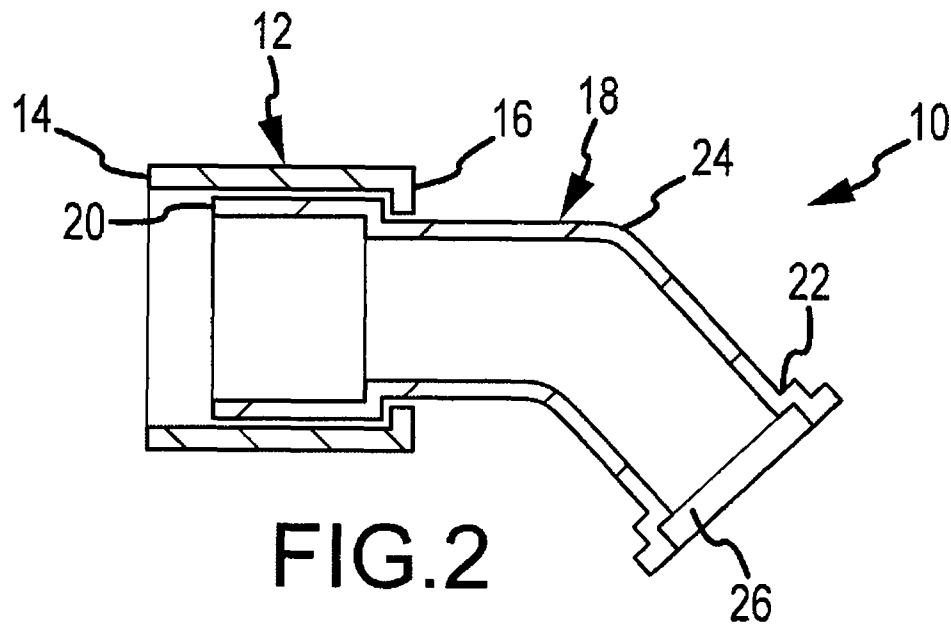
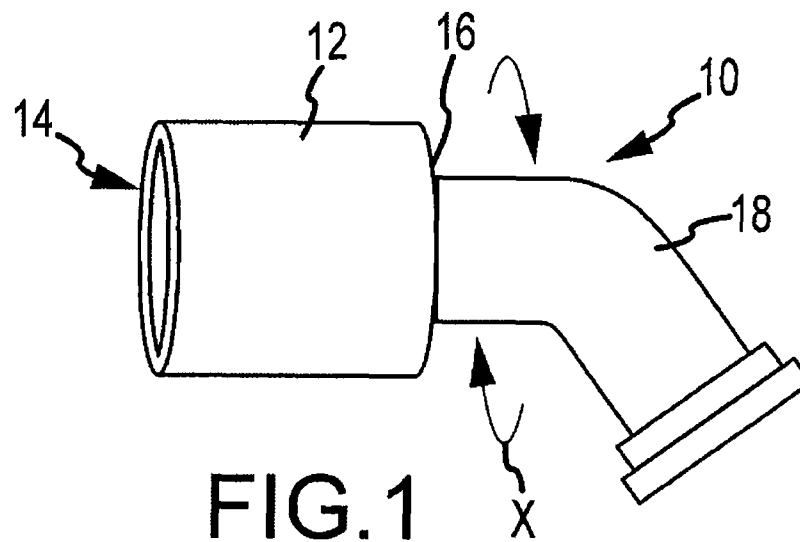
18 Claims, 4 Drawing Sheets

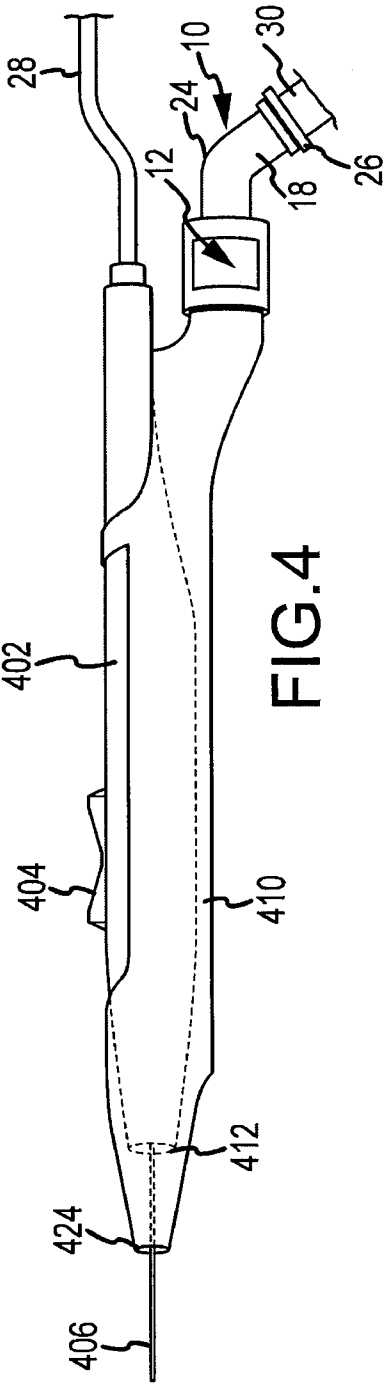
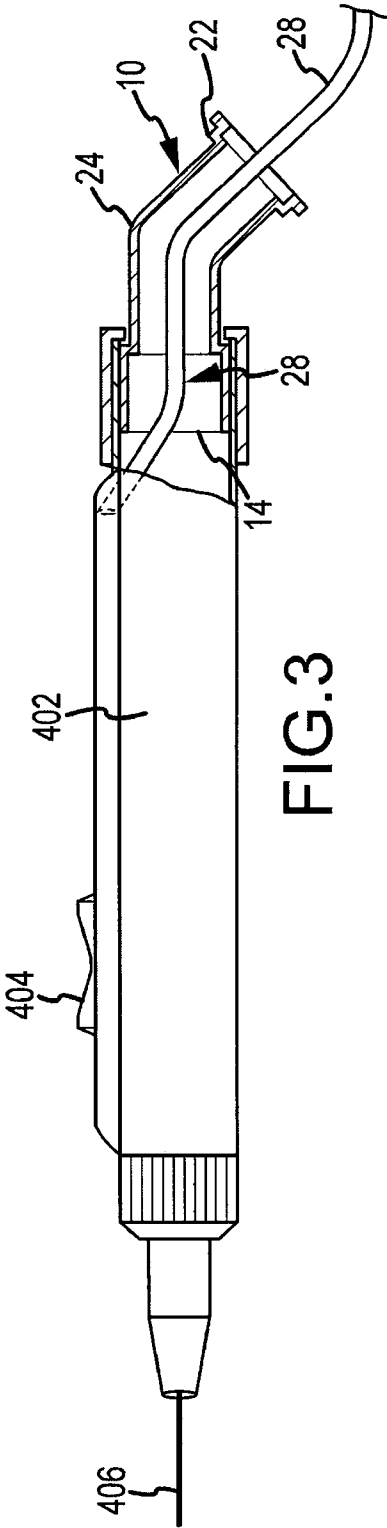
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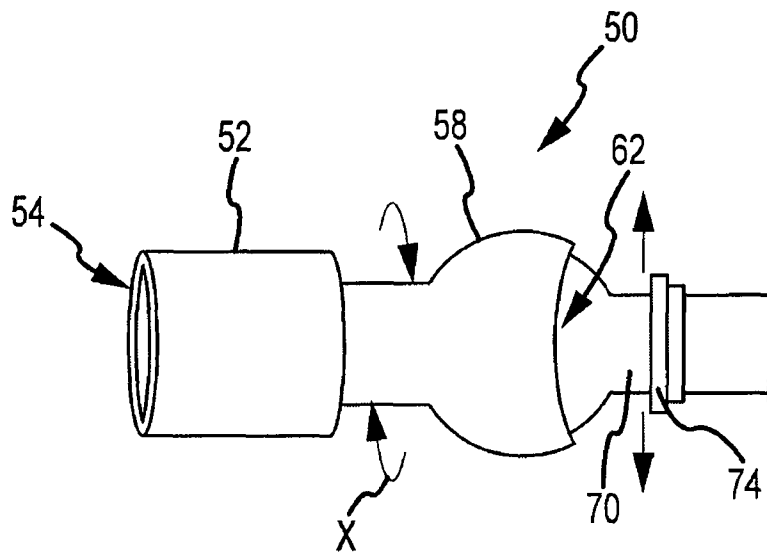


FIG. 5

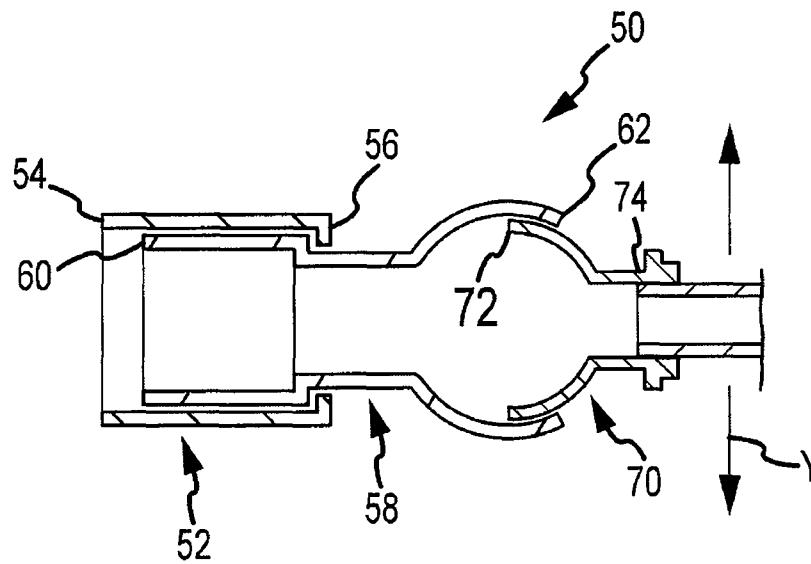
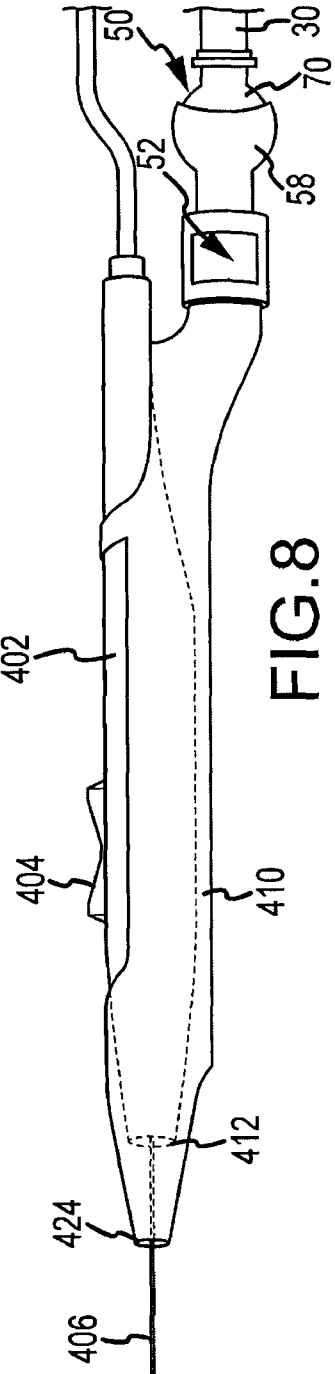
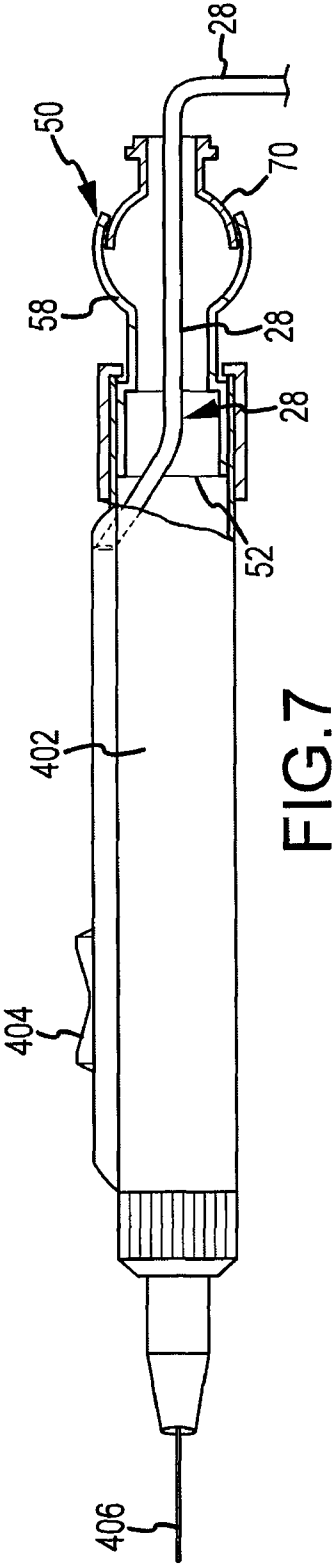


FIG. 6



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SWIVEL DEVICE FOR ELECTROSURGERY PENCIL AND SURGICAL SMOKE EVACUATION

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation-in-part of currently pending application having Ser. No. 11/164,712, filed Dec. 2, 2005 which is herein incorporated in its entirety.

FIELD OF INVENTION

The present invention relates generally to a swivel apparatus. More specifically, the present invention relates to a swivel apparatus for attachment to or incorporation with the smoke evacuation system of an electro-surgical unit (ESU) pencil, and methods for making the same. The invention also relates to a swivel apparatus that can be incorporated into the connection between an ESU pencil and the electrical cord of the ESU pencil where the ESU pencil may be used either with or without smoke evacuation.

BACKGROUND OF THE INVENTION

The use of ESU pencils for cutting tissue and coagulating blood vessels in surgical procedures is well known. When an ESU pencil is used for cutting or coagulation, smoke is produced. In the past, when a surgeon wanted to evacuate this smoke from the surgical field, the surgeon or an assistant had to hold a plastic suction wand, connected to vacuum tubing, near the site of smoke production. This became cumbersome in many surgical procedures, because two hands were required—one operating the ESU pencil and the other holding the suction device—and because the suction wand often obscured the surgeon's view of the surgical field. Therefore, smoke evacuation devices were developed which were either incorporated directly into the design of an ESU pencil or were attachable to an ESU pencil.

Built-in or attachable smoke evacuation devices have also proved problematic, however. Like the suction wand, these devices must be connected to a vacuum source via a vacuum tube. The vacuum tubing generally used is stiff, corrugated, rubber tubing. Due to its stiffness, the tubing often coils in such a way that it twists the ESU pencil in the hand of the surgeon and pulls down the other end of the ESU pencil. This pulling and twisting of the ESU pencil is problematic in delicate surgical procedures and often requires the surgeon to stop frequently to uncoil the tubing. Therefore, more flexible vacuum tubing has been tried. However, this tubing is either too soft, so that it collapses under suction, or too narrow, so that it obstructs airflow. These various problems with vacuum tubing have led many surgeons to not use built-in or attached smoke evacuation devices on ESU pencils. But the only alternative is the separate suction wand, which is often too cumbersome or visually obstructing. A separate suction wand also requires a second person to hold it on site which many times interferes with the work of the surgeon.

Therefore, a need exists for an improved connection between an ESU pencil's built-in or attached smoke evacuation system and a vacuum tube. Such a connection would allow the vacuum tube to twist and/or swivel without turning the ESU pencil in the surgeon's hand. The vacuum tube may twist in a clockwise and/or counterclockwise direction. This improved connection would reduce the drag (or pulling down of) the distal end of the ESU pencil (i.e. that end of the ESU pencil opposite the electrode). In addition, the vacuum tube

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may also pivot in vertical up and down directions. The connection would also remain airtight, so that the force of the smoke evacuation system's vacuum is not reduced.

A need also exists for an improved connection between an ESU pencil and the electrical cord attached to the ESU pencil that allows the electrical cord to twist thereby facilitating a surgeon's use of the ESU pencil by reducing the drag or pulling down of the distal end of the ESU pencil (i.e. that end of the ESU pencil opposite the electrode).

SUMMARY OF THE INVENTION

The present invention is directed to a swivel device which includes a fixed member which can be attached to at least one of an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment, and a rotating member having a first end, a second end, and an angled portion located between the first and second ends. The first end of the rotating member is coupled to an interior of the fixed member. The angled portion of the rotating member may form approximately a 45 degree angle.

In one aspect of the invention, the fixed member and rotating member may be hollow tubular members each having first and second ends where the second end of the fixed member fits precisely around the first end of the rotating member thereby allowing rotation of the rotating member within the fixed member. In order to perform smoke evacuation, the second end of the rotating member is coupled to a vacuum tube such that the rotating member forms a leak proof connection with the vacuum tube. The rotating member preferably has a smooth interior cylindrical surface for conducting smoke and debris to the vacuum tube.

In one exemplary embodiment of the invention, the fixed member is capable of removable attachment to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, and an exhaust port of an ESU pencil smoke evacuation shroud attachment.

In another exemplary embodiment, at least a portion of an electrical cord for providing power to the ESU pencil is contained within the fixed member and the rotating member. In addition, smoke evacuation may or may not also occur through the fixed member and the rotating member.

Yet another exemplary embodiment of the swivel device of the present invention includes a fixed member attached to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment, a rotating member with first and second ends where the first end is coupled to an interior of the fixed member and the second end has a cup like shape, and a pivoting member having first and second ends where the first end includes a cup like shape and is coupled to an interior of the second end of the rotating member. Like the above described exemplary embodiments, the fixed member may be capable of removable attachment to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment. The fixed member, rotating member, and pivoting member may all be hollow and each include first and second ends such that the second end of the fixed member fits precisely around the first end of the rotating member to allow rotation of the rotating member within the fixed member and the second end of the rotating member fits precisely within the

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first end of the pivoting member to allow the pivoting member to pivot in at least a vertical up and down direction.

BRIEF DESCRIPTION OF THE DRAWINGS

A more complete understanding of the present invention may be derived by referring to the detailed description and claims when considered in connection with the following illustrative figures, which may not be to scale. In the following figures, like reference numbers refer to similar elements throughout the figures.

FIG. 1 is a perspective view of one exemplary embodiment of a swivel device according to the present invention, for attachment to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment.

FIG. 2 is a cross-sectional view of the swivel device in FIG. 1.

FIG. 3 is a side view of an ESU pencil with an electrical cord for powering the ESU pencil permanently incorporated in the swivel device shown in FIGS. 1-2 with the electrical cord shown in phantom.

FIG. 4 is a perspective view of an ESU pencil with a smoke evacuation shroud attachment shown connected to the swivel device shown in FIGS. 1-2.

FIG. 5 is another exemplary embodiment of a swivel device according to the present invention, for attachment to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment.

FIG. 6 is a cross-sectional view of the swivel device shown in FIG. 5.

FIG. 7 is a side view of an ESU pencil with an electrical cord for powering the ESU pencil permanently incorporated in the swivel device shown in FIGS. 5-6 with the electrical cord shown in phantom.

FIG. 8 is a perspective view of an ESU pencil with a smoke evacuation shroud attachment shown connected to the swivel device shown in FIGS. 5-6.

DETAILED DESCRIPTION

One exemplary embodiment of the swivel device 10 of the present invention is shown in FIG. 1. Swivel device 10 includes a fixed member 12 having a first end 14 and a second end 16, and rotating member 18 which is coupled to an interior of the fixed member 12. Rotating member 18 includes a first end 20 (see FIG. 2), a second end 22, and an angled portion 24 located between first end 20 and second end 22. Second end 22 of rotating member 18 may further include a collar 26 which is capable of forming a leak proof connection with a vacuum tube (see FIG. 4).

Fixed member 12 and rotating member 18 may comprise hollow tubular members with smooth interior cylindrical surfaces which facilitate evacuation of smoke from a surgical site through a vacuum tube. Second end 16 of fixed member 12 is friction fit around first end 20 of rotating member 18 thereby allowing rotation of rotating member 18 within fixed member 12 as indicated by arrow X. The rotating member 18 may rotate in both clockwise and counterclockwise directions. This rotation of rotating member 18 which is connected to a vacuum tube (see FIG. 4) reduces the drag (or pulling down of) the distal end of the ESU pencil (i.e., the end of the ESU pencil opposite the electrode).

Fixed member 12 and rotating member 18 of swivel device 10 are preferably made of a sturdy and durable material which

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enables the friction fit of rotating member 18 within fixed member 12 while still allowing for the rotation of rotating member 18 within fixed member 12. Examples of such materials include, but are not limited to, polymers, plastics, fiber-glass, etc.

A side view of an ESU pencil 402 with an electrical cord for powering the ESU pencil 402 permanently incorporated in swivel device 10 with the electrical cord 28 shown in phantom is depicted in FIG. 3. Electrical cord 28 is routed through swivel device 10 so that electrical cord 28 does not twist the ESU pencil in the hand of the surgeon during an electrosurgery procedure. In another exemplary embodiment, ESU pencil 402 may comprise a telescopic ESU pencil as shown in FIG. 3 which may accommodate smoke evacuation through its interior. In the event that smoke evacuation is accommodated through an interior of ESU pencil 402, swivel device 10 may also be coupled to a vacuum tube as shown in FIG. 4 to evacuate smoke from the surgical site.

FIG. 4 shows a perspective view of an ESU pencil 402 with a smoke evacuation shroud attachment 410 shown connected to swivel device 10 of the present invention. Collar 26 of rotating member 18 fits over vacuum tube 30 to create an airtight connection between vacuum tube 30 and rotating member 18. Alternatively, second end 22 of rotating member 18 may be tapered to fit inside of vacuum tube 30, also creating an airtight connection between rotating member 18 and vacuum tube 30. Like the connection of swivel device 10 with ESU pencil 402 shown in FIG. 3, the connection between swivel device 10 and smoke evacuation shroud attachment 410 reduces the drag, or pulling down of, the distal end of the smoke evacuation shroud attachment 410 while the surgeon performs an electrosurgery procedure.

Another exemplary embodiment of swivel device 50 in accordance with the present invention is shown in FIGS. 5-6. Swivel device 50 may be attached to an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, or an exhaust port of an ESU pencil smoke evacuation shroud attachment. Swivel device 50 includes a fixed member 52 having a first end 54 and second end 56, a rotating member 58 having a first end 60 and a second end 62, and a pivoting member 70 having a first end 72 and second end 74. Second end 56 of fixed member 52 is friction fit around first end 60 of rotating member 58 such that rotating member 58 is capable of rotating within fixed member 52. Second end 62 of rotating member 58 comprises an open-ended hollow half sphere shape, or cup like shape. In addition, first end 72 of pivoting member 70 also comprises an open-ended hollow half sphere shape, or cup like shape, which is friction fit within an interior of the cup like shape of first end 60 of rotating member 58 thereby allowing pivoting member 70 to pivot within rotating member 58 at least in a vertical up and down direction as indicated by arrow Y. In addition, pivoting member 70 may also pivot in a number of different directions relative to second end 62 of rotating member 58. This exemplary embodiment of swivel device 10 of the present invention provides a broader range of motion for the movement of a vacuum tube 30 or electrical cord 28 with respect to an ESU pencil 402 or smoke evacuation shroud attachment 410 to further decrease drag on the distal end of the ESU pencil or smoke evacuation shroud attachment 410 and to reduce twisting of vacuum tube 30 and/or electrical cord 28 while a surgeon performs an electrosurgery procedure.

With respect to the exemplary embodiment of swivel device 50 shown in FIGS. 5-6, the present invention also contemplates a swivel device which includes only rotary member 58 and pivoting member 70 whereby first end 60 of

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rotating member **58** would be attached in a leak proof manner to an outer body of an ESU pencil, and exhaust port of an ESU pencil with an integrated smoke evacuation system, or a exhaust port of an ESU pencil smoke evacuation shroud attachment. The connection between second end **62** of rotating member **58** and first end **72** of pivoting member **70** would then provide the sole means for vacuum tube **30** and/or electrical cord **28** to swivel, rotate, and/or pivot in relation to ESU pencil **402** or ESU pencil smoke evacuation shroud attachment **410**.

FIG. **7** is a side view of an ESU pencil with an electrical cord for powering the ESU pencil permanently incorporated in swivel device **50** shown in FIGS. **5-6** with electrical cord **28** shown in phantom. Electrical cord **28** is routed through swivel device **50** so that electrical cord **28** does not twist the ESU pencil in the hand of the surgeon during an electrosurgery procedure. In another exemplary embodiment, ESU pencil **402** may comprise a telescopic ESU pencil as shown in FIG. **7** which may accommodate smoke evacuation through its interior. In the event that smoke evacuation is accommodated through an interior of ESU pencil **402**, swivel device **50** may also be coupled to a vacuum tube as shown in FIG. **8** to evacuate smoke from the surgical site.

A perspective view of an ESU pencil with a smoke evacuation shroud attachment shown connected to swivel device **50** is shown in FIG. **8**. Second end **74** of pivoting member **70** is coupled to vacuum tube **30** to create an airtight connection between vacuum tube **30** and pivoting member **70**. Second end **74** of rotating member **70** may be tapered to fit inside of vacuum tube **30**. Like the connection of swivel device **50** with ESU pencil **402** shown in FIG. **7**, the connection between swivel device **50** and smoke evacuation shroud attachment **410** reduces the drag, or pulling down of, the distal end of the smoke evacuation shroud attachment **410** while the surgeon performs an electrosurgery procedure.

Operation

Referring to FIG. **4**, before beginning a surgical procedure, the second end **22** of rotating member **18** is connected to the vacuum tube **30** which is connected to a vacuum source (not shown) and the power cord **28** for the ESU pencil **402** is connected to a power source (not shown). When desired, the surgeon then uses hand switch **404** to send radio frequency energy to the ESU pencil's **402** electrode **406**, for cutting and coagulation. When the vacuum source is activated, smoke and debris from cutting and coagulation are sucked into the exhaust opening **424** at the distal end of nozzle **412** of the ESU pencil's **402** smoke evacuation shroud attachment **410**. The smoke and debris then travel through the smoke evacuation shroud attachment **410**, swivel device **10**, and vacuum tube **30**, to a vacuum canister (not shown). The operation of the ESU pencil **402** with smoke evacuation shroud attachment **410** is described in full detail in U.S. Pat. Nos. 5,836,944, 6,099,525, and 6,124,995.

It will be understood by one skilled in the art that second end **16** of fixed member **12** and first end **20** of rotating member **18** may take the form of alternative configurations and shapes to enable an airtight seal between fixed member **12** and rotating member **18**. For example, second end **16** of fixed member **12** may take the shape and form of a larger outer-diameter portion of the fixed member as described in U.S. patent application having Ser. No. 11/164,712, filed Dec. 2, 2005. In addition, first end **20** of rotating member **18** may include an inverted distal end on the interior surface of the rotating member and a central inversion on the exterior surface of the

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rotating member as previously described in detail in U.S. patent application having Ser. No. 11/164,712, filed Dec. 2, 2005.

The present invention has been described above with reference to exemplary embodiments. However, those skilled in the art, having read this disclosure, will recognize that changes and modifications may be made to the exemplary embodiments without departing from the scope of the present invention. For example, the swivel device of the present invention may also be used or incorporated with laser or fiber optic surgical pencils that are employed along with suction devices to eliminate smoke and debris from the surgical site. These and other changes or modifications are intended to be included within the scope of the present invention, as expressed in the following claims.

The invention claimed is:

1. A swivel device comprising:

a fixed member attached to at least one of an ESU pencil and an exhaust port of an ESU pencil with an integrated smoke evacuation system; and

a rotating member having a first end, a second end, and an angled portion located between the first and second ends wherein the first end is coupled to an interior of the fixed member and at least a portion of an electrical cord for providing power to said ESU pencil or said ESU pencil with an integrated smoke evacuation system is contained within the fixed member and the rotating member.

2. The apparatus of claim 1 wherein the angled portion of the rotating member comprises approximately a forty five degree angle.

3. The apparatus of claim 1 wherein the fixed member comprises a hollow tubular member having a first end and a second end.

4. The apparatus of claim 3 wherein the rotating member comprises a hollow tubular member and the second end of the fixed member fits precisely around the first end of the rotating member thereby allowing rotation of the rotating member within the fixed member.

5. The apparatus of claim 1 wherein the second end of the rotating member is capable of forming a leak proof connection with a vacuum tube.

6. The apparatus of claim 5 wherein the rotating member has a smooth interior cylindrical surface for conducting smoke and debris to the vacuum tube.

7. The device of claim 1 wherein said fixed member is capable of removable attachment to at least one of said ESU pencil and said exhaust port of an ESU pencil with an integrated smoke evacuation system.

8. A swivel device comprising:

a fixed member attached to at least one of a group consisting of an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, and an exhaust port of an ESU pencil smoke evacuation shroud attachment;

a rotating member having a first end and a second end wherein the first end is coupled to an interior of the fixed member and the second end comprises a cup like shape; and

a pivoting member having a first end and a second end wherein the first end comprises a cup like shape and is coupled to an interior of the second end of the rotating member.

9. The apparatus of claim 8 wherein the rotating member comprises a hollow tubular member and the second end of the fixed member fits precisely around the first end of the rotating member thereby allowing rotation of the rotating member within the fixed member.

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10. The apparatus of claim 9 wherein the pivoting member comprises a hollow tubular member and the second end of the rotating member fits precisely within the first end of the pivoting member thereby allowing the pivoting member to pivot in at least a vertical up and down direction.

11. The apparatus of claim 10 wherein the rotating member and the pivoting member each have a smooth interior cylindrical surface for conducting smoke and debris to the vacuum tube.

12. The apparatus of claim 8 wherein the second end of the pivoting member is capable of forming a leak proof connection with a vacuum tube.

13. The device of claim 8 wherein said fixed member is capable of removable attachment to at least one of the group consisting of an outer body of an ESU pencil, an exhaust port of an ESU pencil with an integrated smoke evacuation system, and an exhaust port of an ESU pencil smoke evacuation shroud attachment.

14. The device of claim 8 wherein at least a portion of an electrical cord for providing power to the ESU pencil is contained within the fixed member and the rotating member.

15. A method for making a swivel device comprising the steps of:

providing a fixed hollow member having a first end and a second end wherein the first end is capable of attachment to at least one of an ESU pencil and an exhaust port of an ESU pencil with an integrated smoke evacuation system;

providing a rotating hollow member having a first end and a second end;

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coupling the first end of the rotating hollow member to an interior surface of the second end of the fixed hollow member;

providing a pivoting member having a first end and a second end; and

coupling the first end of the pivoting member to an interior of the second end of the rotating member.

16. The method of claim 15 wherein the step of providing a rotating hollow member comprises providing a rotating hollow member having a first end and a second end wherein the second end of the rotating member is capable of forming a leak proof connection with a vacuum tube.

17. The method of claim 15 wherein the second end of the rotating member and the first end of the pivoting member each comprise a cup like shape wherein the second end of the rotating member fits precisely within the first end of the pivoting member thereby allowing the pivoting member to pivot in at least a vertical up and down direction.

18. A method for making a swivel-based surgical pencil comprising the steps of:

attaching a first end of a fixed member to at least one of an outer body of an ESU pencil and an exhaust port of an ESU pencil with an integrated smoke evacuation system; and

coupling a first end of a rotating member to an interior surface of a second end of the fixed member such that at least a portion of an electrical cord for providing power to said ESU pencil or said ESU pencil with an integrated smoke evacuation system is contained within the fixed member and the rotating member.

* * * * *

EXHIBIT C



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September 5, 2013

RECEIVED

**BY CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

SEP 12 2013

**LEGAL
DEPT.**

CONMED Corporation
Daniel S. Jonas, Executive V.P. of Legal Affairs
and General Counsel
525 French Road
Utica, NY 13502

Re: GoldVac® Electrosurgery pencil

Dear Mr. Jonas:

This firm represents I.C. Medical, Inc. with respect to their intellectual property matters. I.C. Medical, Inc. is the owner of U.S. Patent No. 7,935,109 issued on May 3, 2011, a copy of which is enclosed.

As you know, our client and your company were both involved in previous litigation in the U.S. relating to your GoldVac® electrosurgery pencil and other IC Medical issued patents relating to electrosurgery pencils. That litigation resulted in a joint settlement agreement which included an Agreement between ConMed Corporation and I.C. Medical, Inc. dated June 7, 2010 that included a pre-suit notification clause. That pre-notification clause states that I.C. Medical will notify ConMed in writing of any claim against ConMed prior to filing suit and that ConMed will have 15 days in which to respond during which I.C. Medical will not file suit. The pre-suit notification clause also states that ConMed will not file any declaratory judgment action for 20 days after receiving notice.

This letter hereby serves as written notice to ConMed that ConMed is infringing I.C. Medical's U.S. Patent No. 7,935,109. However, at this stage, and given the past litigation history between ConMed and I.C. Medical we would like to speak with you regarding potentially resolving this issue. I ask that you contact me within 10 days of receipt of this letter to discuss whether a resolution is possible.

Please note that if we do not hear from you within the time set out in the pre-suit notification clause (15 days), we shall consider our client to be free to commence suit against ConMed, and we shall recommend that they do so.

Very truly yours,

Zeman-Mullen & Ford, LLP

A handwritten signature in cursive script that reads 'Laura J. Zeman-Mullen'.

Laura J. Zeman-Mullen

LJZ/kb

Enclosures

cc: I.C. Medical

EXHIBIT D



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September 30, 2013

WITHOUT PREJUDICE

Daniel S. Jonas, Esq.
Executive Vice President – Legal Affairs
General Counsel
525 French Road
Utica, NY 13502

Dear Mr. Jonas,

Thank you for your reply dated September 17, 2013.

I am writing to address the points you raised in your letter. I appreciate that you did not have an opportunity to conduct a full analysis, but I wished to advise that I disagree with the statements you have made following your preliminary review. My client and I continue to believe that the GoldVac infringes IC Medical's US patent 7,935,109 (the "109 Patent").

First, I do not agree with your construction of the term "multifunctional". This term does not relate to the monopolar/bipolar aspect as you alleged. This term relates to the invented device having more than one function – i.e. electrosurgery, smoke evacuation, etc. In this respect, please refer to the claim language, which is itself incompatible with your interpretation of "multifunctional" as meaning "both monopolar and bipolar". In particular, I refer you to claim 5, which describes "The multifunctional electrosurgery pencil of claim 1 wherein said electrode is a bipolar electrode." If "multifunctional" could be properly construed as "monopolar and bipolar", this claim would not have been allowed in its current form, and the claims as a whole would be internally inconsistent.

In response to your request for a claim chart, please see the attached.

Regarding your allegation of inequitable conduct relating to the '109 Patent, we strongly disagree with the characterizations you have made of our client's actions and the prosecution history. In any event, none of the points you raised would meet the test for inequitable conduct, which is set out in the *Therasense* case. Intent and materiality would be required to be proven. We do not believe that any Court reviewing the points you have raised, even accepting the characterizations you have placed on them, could reasonably conclude that any of them rise to the level of inequitable conduct.

Daniel S. Jonas
September 30, 2013
Page 2

We are therefore confident that if Court proceedings were necessary, the 109 Patent would be upheld as valid, and the GoldVac found to infringe.

However, we agree that it makes sense to undertake discussions with one another before spending further significant funds on litigation. Our client's primary focus is ConMed's infringing activities of manufacture and sale in the US. However, we do recognize that the Canadian litigation will soon be entering a more cost and time-intensive phase, and it therefore makes sense to consider a global settlement at this time.

We believe that the specific terms of settlement would be best discussed live, but can provide the following terms to frame our discussion. We believe these terms would provide a reasonable, global resolution of the ongoing disputes:

- IC Medical to refrain from commencing further litigation in the US against ConMed in respect of the 109 Patent and any patents claiming priority to that patent;
- ConMed would be permitted to continue the manufacture and sale of the GoldVac within the US, but would transition out of the Canadian market until the relevant Canadian patents expire;
- The relevant releases would be signed to discontinue the Canadian case;
- ConMed would pay a one time \$125,000 fee for a fully paid-up license for all of IC Medical's existing US patents which could read on the currently existing GoldVac and any patent applications claiming priority from those patents.
- All parties to bear their own legal costs to date.

We look forward to discussing the above with you.

Very truly yours,

Zeman-Mullen & Ford, LLP

A handwritten signature in blue ink, reading "Laura J. Zeman-Mullen", with a long horizontal flourish extending to the right.

Laura J. Zeman-Mullen

LJZ/kb
Enclosure
cc: I.C. Medical

September 25, 2013

WITHOUT PREJUDICE

Infringement of U.S. Patent No. 7,935,109

Claim	Element	GOLDVAC
1.	A multifunctional electrosurgery pencil for use with an energy source comprising:	The Goldvac is a multifunctional electrosurgery pencil for use with an energy source (an electrosurgery unit).
	an electrode;	An electrode is present.
	a handpiece with means for connecting said electrode to said energy source;	A handpiece connects the electrode to the electrosurgery unit.
	telescopic member means contained within said handpiece for adjusting the length of said telescopic member means extending from said handpiece wherein at least a portion of said electrode is contained within said telescopic member means; and	The Goldvac incorporates a length-adjustable telescoping tube within the handpiece. The telescoping tube extends from the handpiece and contains a portion of the electrode.
	smoke evacuation means coupled to said handpiece for removing smoke and debris produced during a medical procedure using said electrosurgery pencil and energy source.	The Goldvac incorporates a connection to smoke evacuation tubing.
2.	The multifunctional electrosurgery pencil of claim 1 wherein said energy source is an electrosurgery unit.	The energy source used with the Goldvac is an electrosurgery unit.
6.	A multifunctional telescopic electrosurgery pencil for use with an energy source comprising:	The Goldvac is a multifunctional electrosurgery pencil for use with an electrosurgery unit.
	a main body having a first end and a second end in continuous communication with one another wherein the second end is capable of being coupled to smoke evacuation means for removing smoke and debris produced during a medical procedure using said electrosurgery pencil and energy source;	The Goldvac has a main body with connected first and second ends, the second end capable of connection to smoke evacuation tubing to remove smoke and debris produced during the surgery.
	a movable telescopic body circumferentially	The Goldvac incorporates a

	contained within the first end of the main body; and	movable telescoping tube contained within the first end of the main body.
	an electrode contained within at least a portion of the movable telescopic body such that it is capable of being in electrical contact with the energy source.	The Goldvac incorporates an electrode that is contained within the telescopic body, and is capable of being in electrical contact with the electrosurgery unit.
7.	The multifunctional electrosurgery pencil of claim 6 wherein said energy source is an electrosurgery unit.	The energy source used with the Goldvac is an electrosurgery unit.

EXHIBIT E



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October 5, 2013

WITHOUT PREJUDICE

Via Email (DanielJonas@conmed.com) & Federal Express

Daniel S. Jonas, Esq.
Executive Vice President – Legal Affairs
General Counsel
525 French Road
Utica, NY 13502

Re: ConMed's Goldvac Electrosurgery Pencil and IC Medical Patents

Dear Mr. Jonas:

This correspondence is a follow up on our phone call of Sept. 30, 2013.

As you know, we believe the GoldVac infringes IC Medical's U.S. Patent No. 7,935,109 (the "109 Patent") for the reasons provided earlier. In addition, I direct your attention to IC Medical's U.S. Patent No. 8,414,576 (the '576 Patent) which is directed to a "Swivel Device for Electrosurgery Pencil and Surgical Smoke Evacuation" (copy enclosed). We believe the GoldVac infringes at least claim 18 of the '576 Patent.

I had also advised that I would provide further detail regarding the specific IC Medical patents at issue in the earlier proposed settlement terms. These details are set out below.

- IC Medical to refrain from commencing further claims or counterclaims in the US against ConMed in respect of the '109 and '576 Patents;
- ConMed would be permitted to continue the manufacture and sale of the GoldVac within the US, but would transition out of the Canadian market until the relevant Canadian patents expire;
- The relevant releases would be signed to discontinue the Canadian case and your newly commenced US case;
- ConMed would pay a one time \$125,000 fee for a fully paid-up license for all of IC Medical's existing US patents which could read on the currently existing GoldVac and any patent applications claiming priority from those patents, namely:
 - U.S. Patent No. 7,935,109;
 - U.S. Patent No. 8,414,576;

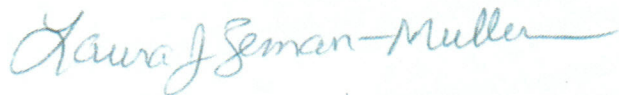
Daniel S. Jonas, Esq.
October 5, 2013
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- U.S. patent application having Serial No. 12/637,194;
 - U.S. patent application having Serial No. 11/164,712; and
 - U.S. patent application having Serial No. 14/028,270.
- All parties to bear their own legal costs to date.

We look forward to discussing the above with you.

Very truly yours,

Zeman-Mullen & Ford, LLP

A handwritten signature in blue ink that reads "Laura J. Zeman-Mullen". The signature is fluid and cursive, with a long horizontal line extending from the end.

Laura J. Zeman-Mullen

LJZ/kb
Enclosure
cc: I.C. Medical, Inc.